



US006402785B1

(12) **United States Patent**
Zdeblick et al.

(10) **Patent No.:** **US 6,402,785 B1**
(45) **Date of Patent:** **Jun. 11, 2002**

(54) **ARTIFICIAL DISC IMPLANT**

(75) Inventors: **Thomas A. Zdeblick**, Middleton, WI (US); **William F. McKay**, Memphis, TN (US)

(73) Assignee: **SDGI Holdings, Inc.**, Wilmington, DE (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/586,308**

(22) Filed: **Jun. 2, 2000**

Related U.S. Application Data

(60) Provisional application No. 60/137,586, filed on Jun. 4, 1999.

(51) **Int. Cl.**⁷ **A61F 2/44**

(52) **U.S. Cl.** **623/17.16; 623/17.15**

(58) **Field of Search** **623/17.15, 17.16**

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,867,728 A	2/1975	Stubstad et al.
3,875,595 A	4/1975	Froning
4,309,777 A	1/1982	Patil
4,349,921 A	9/1982	Kuntz
4,743,256 A	5/1988	Brantigan
4,759,766 A	7/1988	Buettner-Janzen et al.
4,772,287 A	9/1988	Ray et al.
4,863,476 A	9/1989	Shepperd
4,863,477 A	9/1989	Monson
4,904,260 A	2/1990	Ray et al.
4,917,704 A	4/1990	Frey et al.
4,932,969 A	6/1990	Frey et al.

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

FR 2 772 594 6/1999

WO	WO 90/11740	10/1990
WO	WO 95/31946	11/1995
WO	PCT/FR98/02798	12/1998
WO	WO 00/04851	2/2000
WO	WO 00/13620	3/2000

OTHER PUBLICATIONS

Sofamor Danek—The Spine Specialist; “Surgical Technique Using Bone Dowel Instrumentation for Posterior Approach”.

Sofamore Danek—The Spine Specialist; “Surgical Technique Using Bone Dowel Instrumentation for Anterior Approach”.

Schonmayr et al., *Rivista di Neuroradiologia* 12 (Suppl 1): 163–170, 1999; “Prosthetic Disc Nucleus Implants: the Wiesbaden Feasibility Study”.

Ray et al., *Rivista di Neuroradiologia* 12 (Suppl 1): 157–162, 1999, Prosthetic Disc Nucleus Implants.

SR&EF Norfolk, VA 23502, 1996 Patient Information on Replacement of the Disc Nucleus by Raymedica PDN.

Primary Examiner—Corrine McDermott

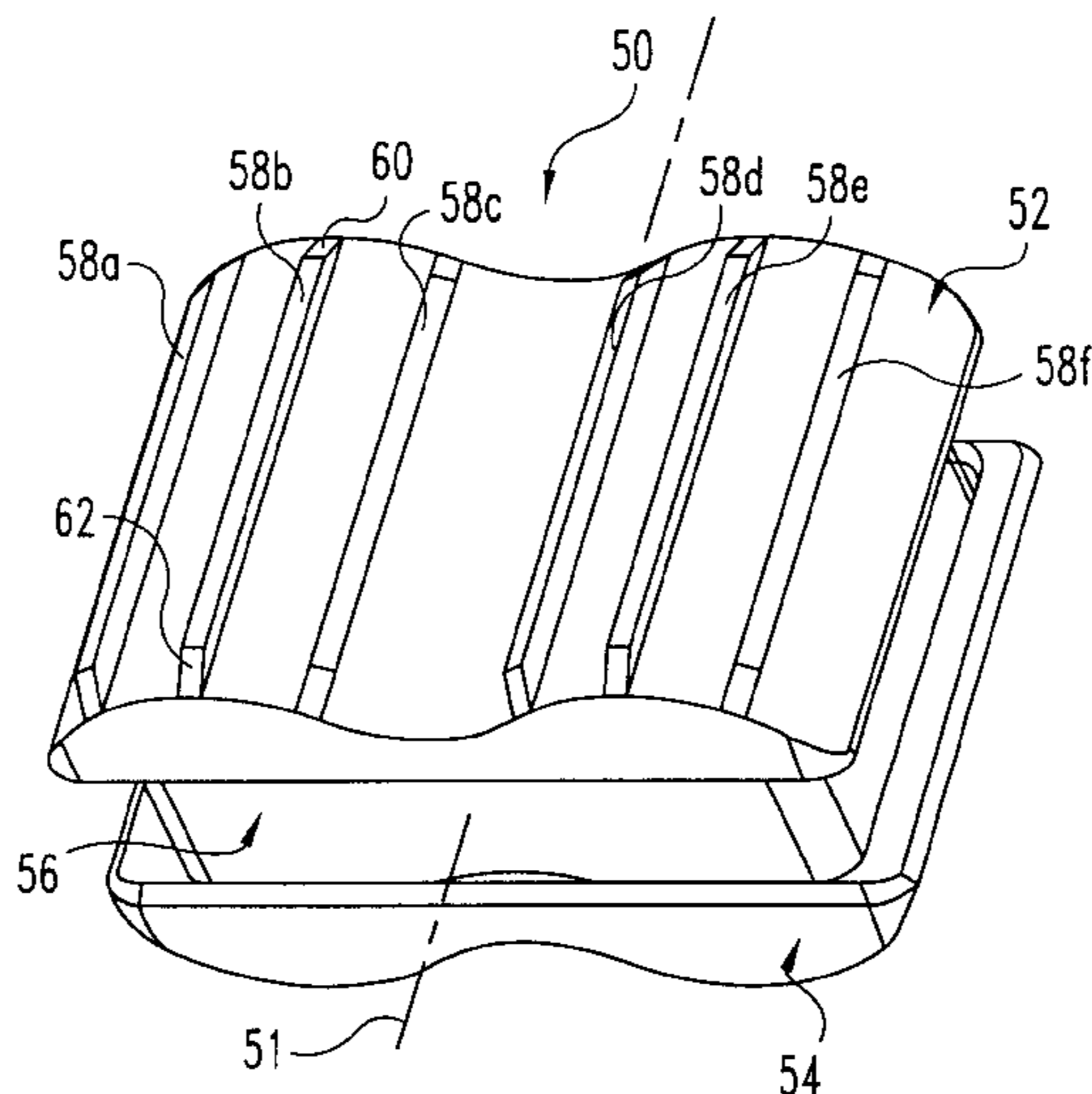
Assistant Examiner—Thomas C. Barrett

(74) *Attorney, Agent, or Firm*—Woodard, Emhardt, Naughton, Moriarty & McNett

(57) **ABSTRACT**

An artificial disc implant includes an upper shell, a lower shell, and a spacer therebetween. The spacer preferably has properties similar to that of a natural spinal disc, while the upper and lower shells form a rigid interface between the implant and the adjacent vertebral bodies. The upper and lower shells can be configured to prevent expulsion of the spacer from the disc space. The implant upper and lower shells may further be configured into partially cylindrical shapes for ease of insertion through an insertion tube as presently known for interbody fusion devices. The devices may further be configured for insertion through a double-barreled insertion tube. Methods and instruments for inserting an artificial disc implant are also provided.

44 Claims, 19 Drawing Sheets



U.S. PATENT DOCUMENTS

4,946,378 A	8/1990	Hirayama et al.	5,545,229 A	8/1996	Parsons et al.
4,997,432 A	3/1991	Keller	5,562,736 A	10/1996	Ray et al.
5,002,576 A	3/1991	Fuhrmann et al.	5,562,738 A	10/1996	Boyd et al.
5,047,055 A	9/1991	Bao et al.	5,645,597 A	7/1997	Krapiva
5,071,437 A	12/1991	Steffee	5,674,295 A	10/1997	Ray et al.
5,171,280 A	12/1992	Baumgartner	5,674,296 A	10/1997	Bryan et al.
5,192,326 A	3/1993	Bao et al.	5,702,450 A	12/1997	Bisserie
5,306,307 A	4/1994	Senter et al.	5,705,780 A *	1/1998	Bao 204/157.15
5,306,308 A	4/1994	Gross et al.	5,785,710 A	7/1998	Michelson
5,314,478 A	5/1994	Oka et al.	5,824,093 A	10/1998	Ray et al.
5,370,697 A	12/1994	Baumgartner	5,824,094 A	10/1998	Serhan et al.
5,401,269 A	3/1995	Buttner-Janzen et al.	5,888,226 A	3/1999	Rogozinski
5,425,773 A *	6/1995	Boyd et al. 623/17	6,019,792 A	2/2000	Cauthen
5,458,643 A	10/1995	Oka et al.	6,113,637 A	9/2000	Gill et al.
5,507,816 A	4/1996	Bullivant	6,113,638 A	9/2000	Williams et al.
5,534,028 A	7/1996	Bao et al.	6,179,874 B1	1/2001	Cauthen
5,534,030 A	7/1996	Navarro et al.			

* cited by examiner

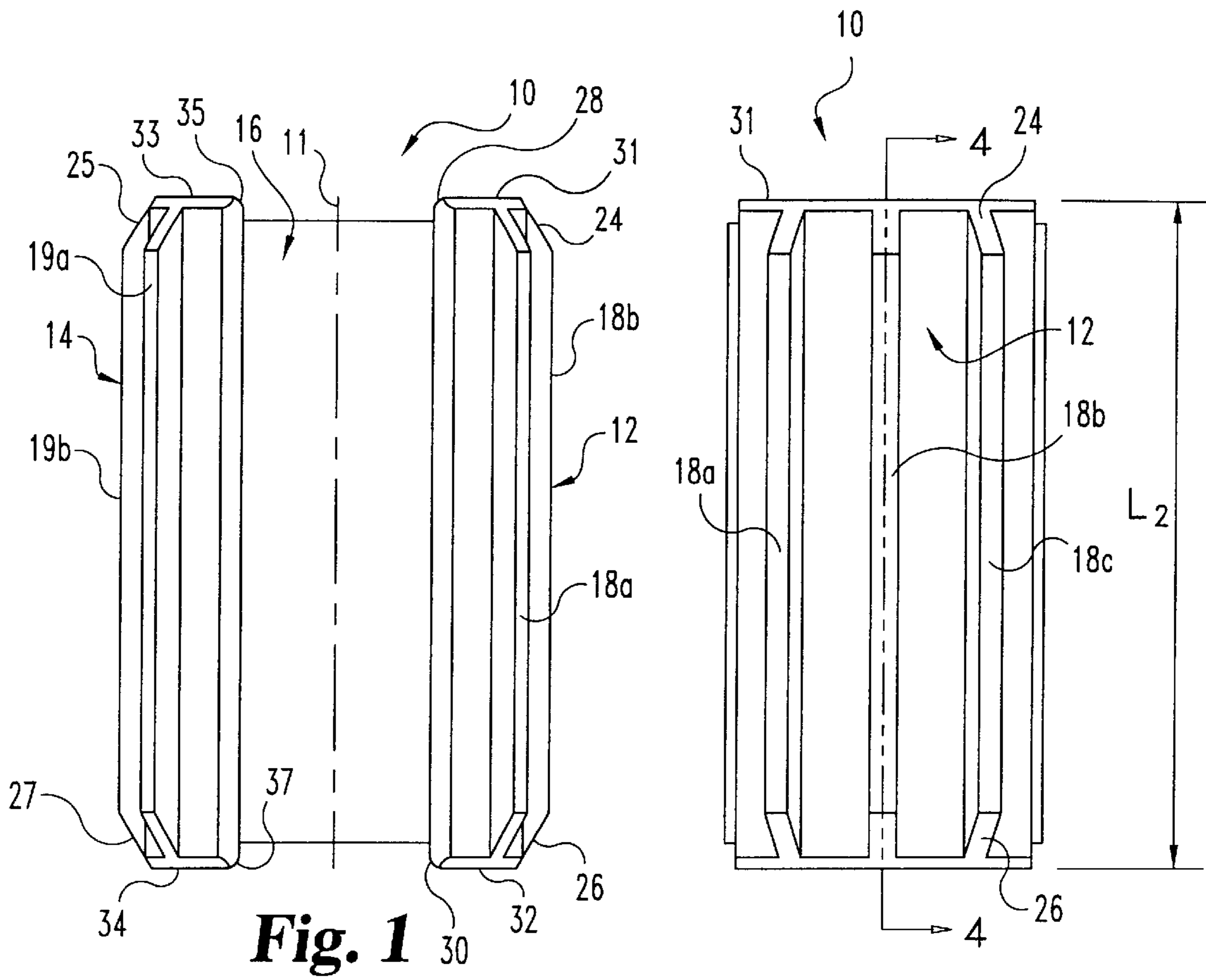


Fig. 1

Fig. 2

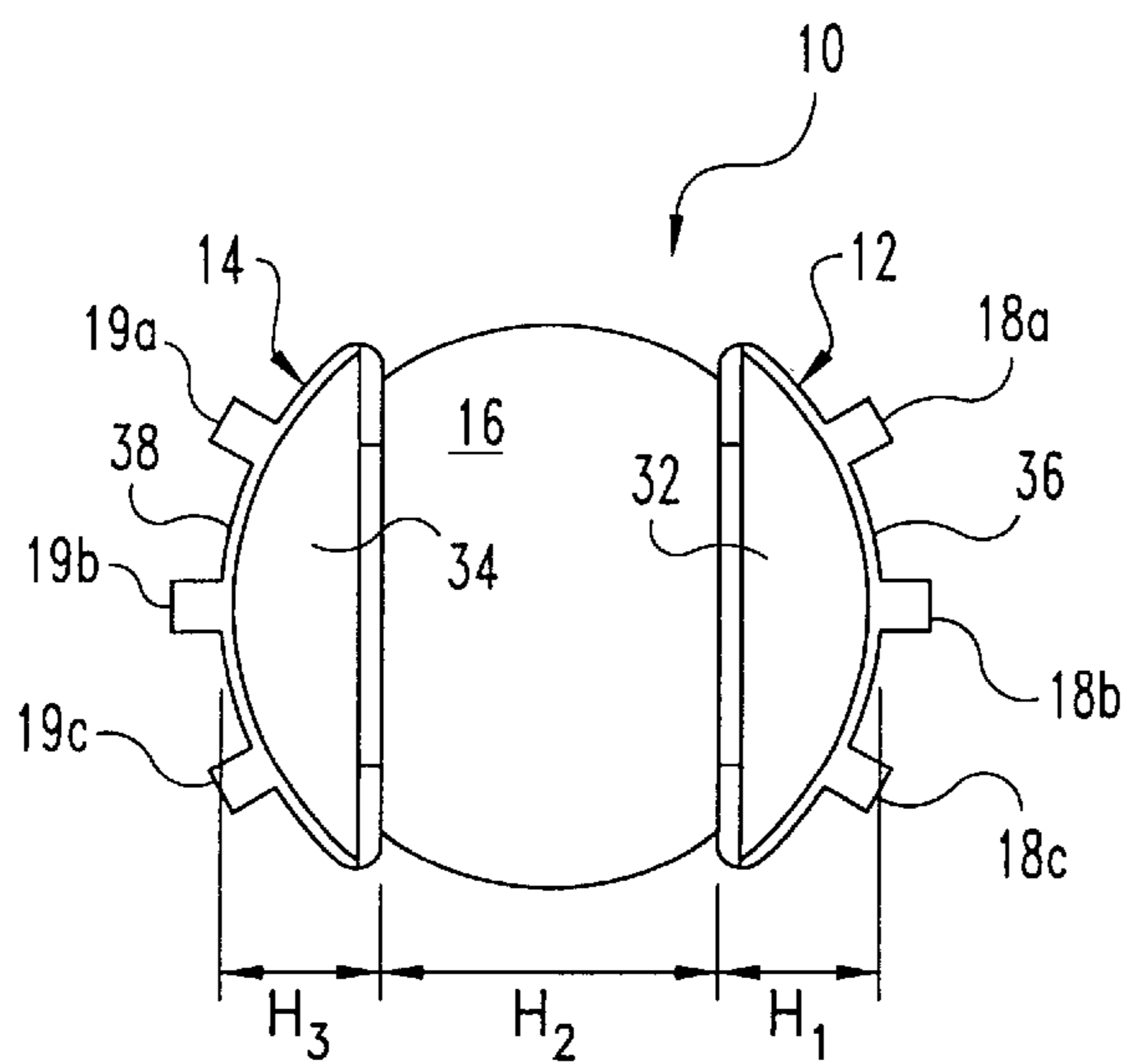
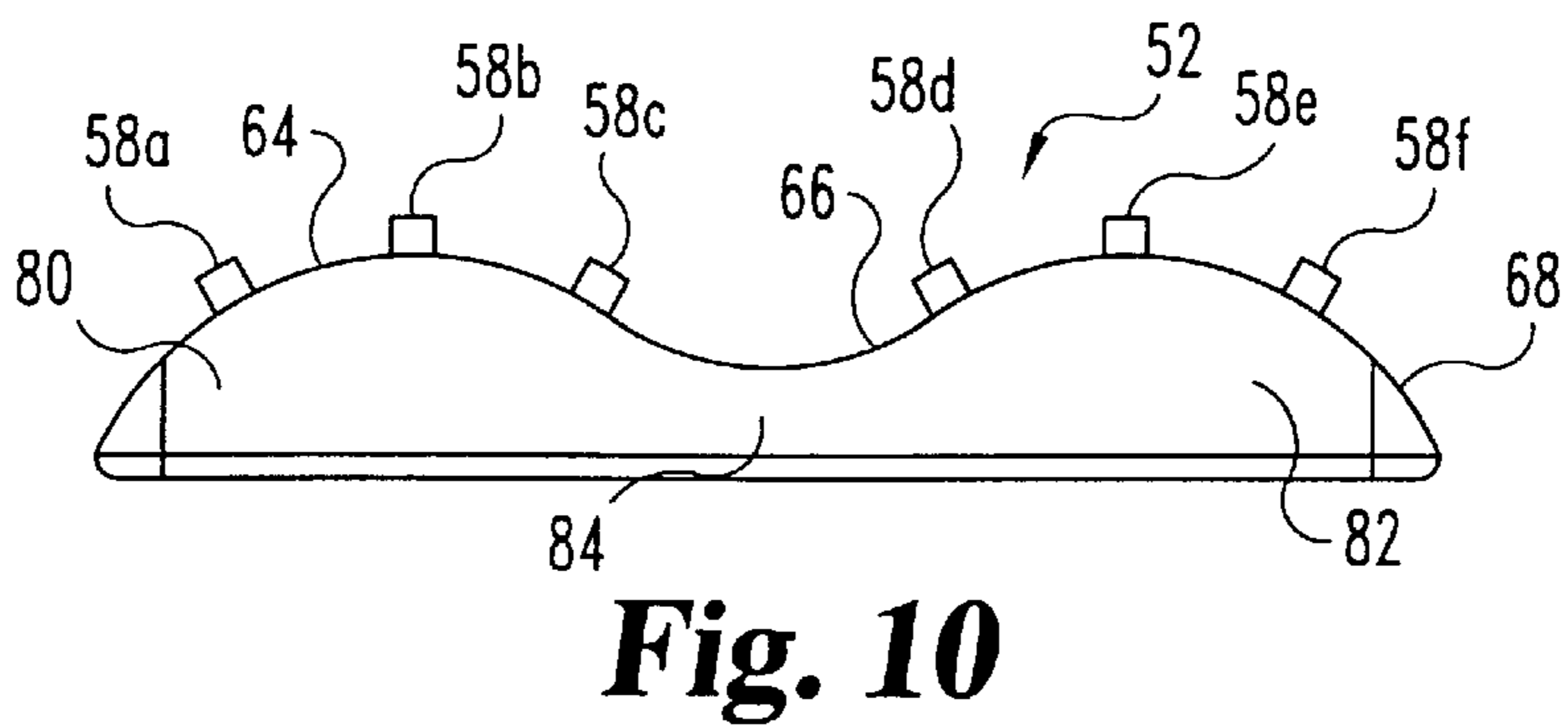
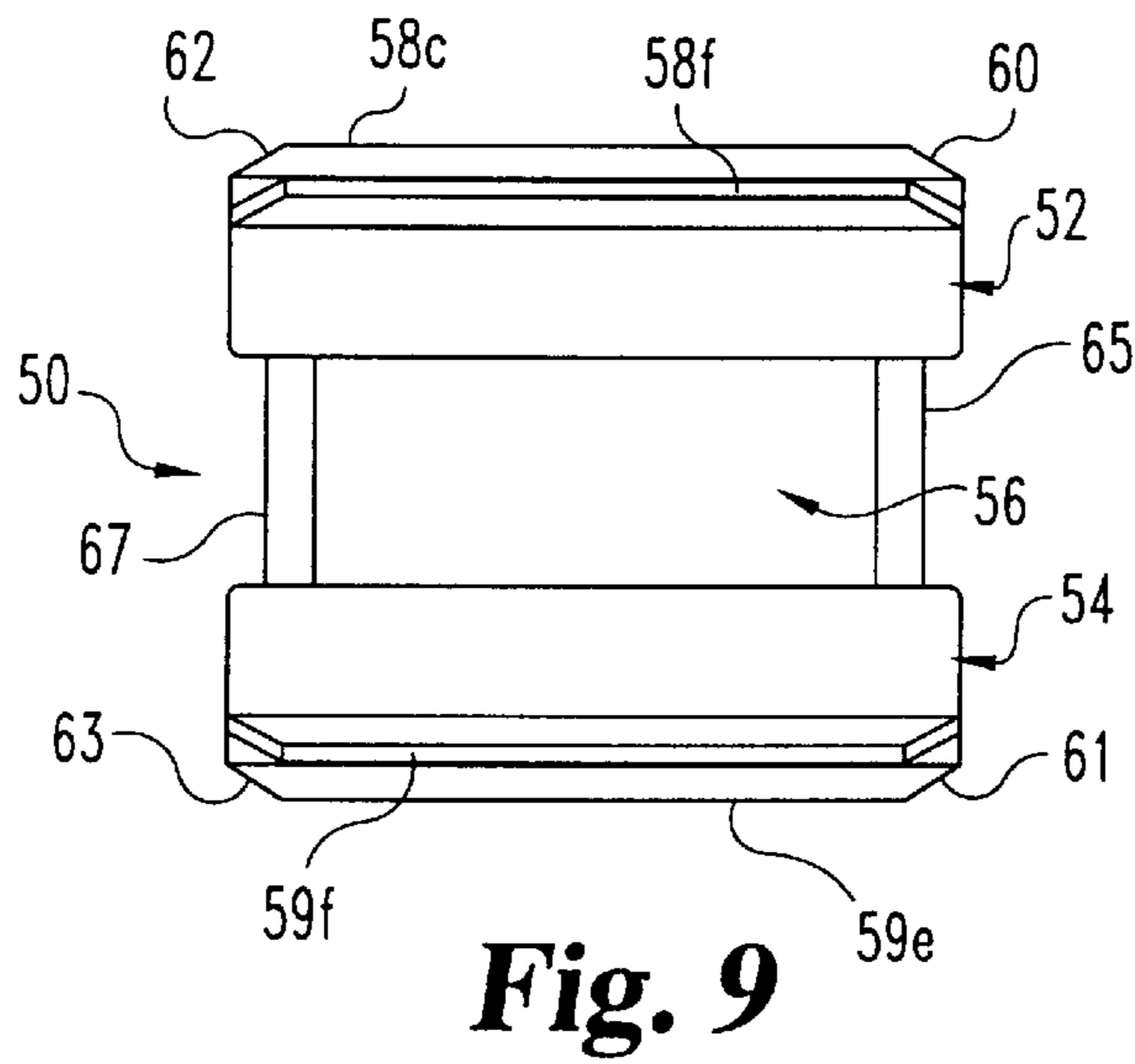
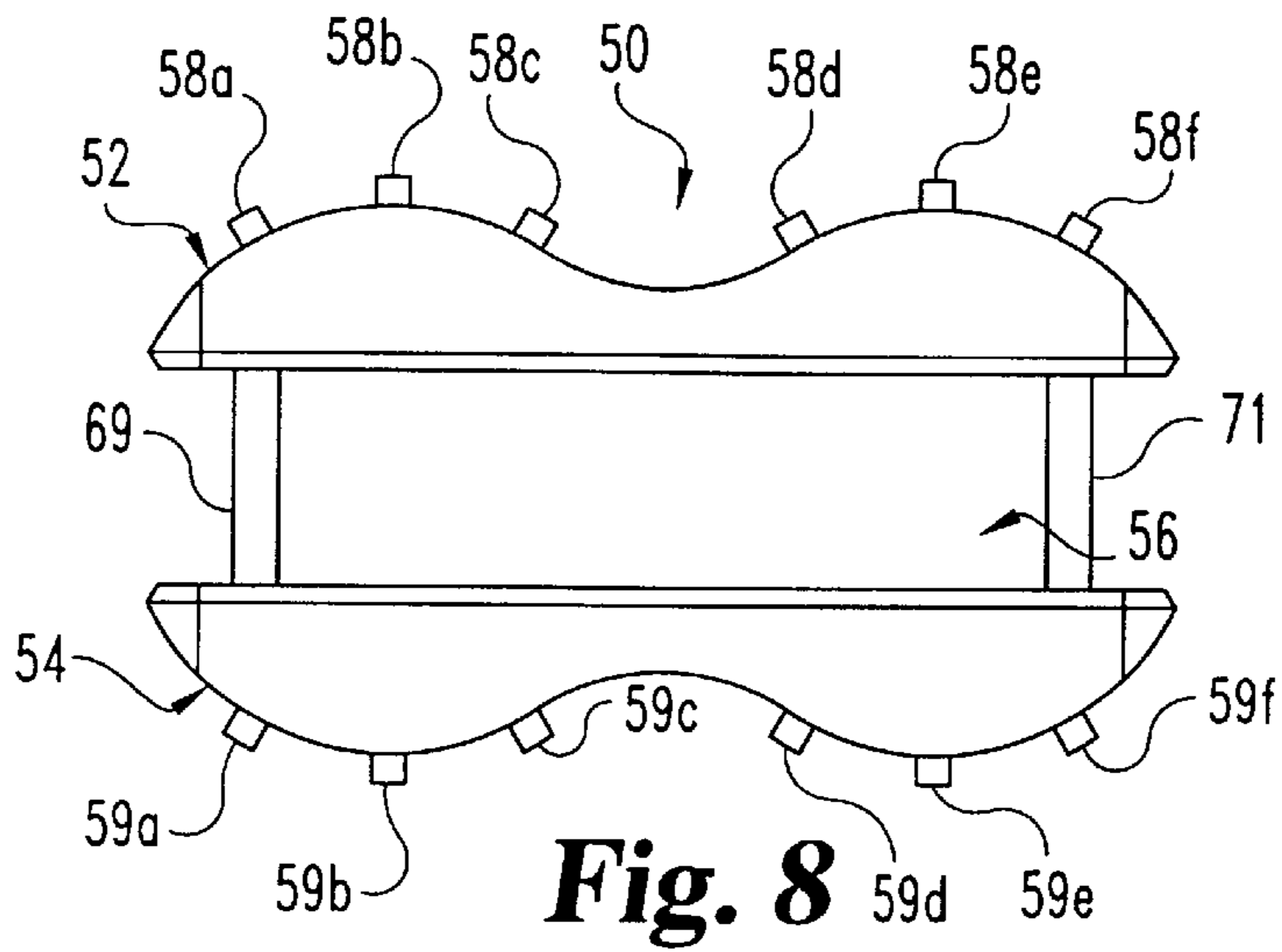


Fig. 3



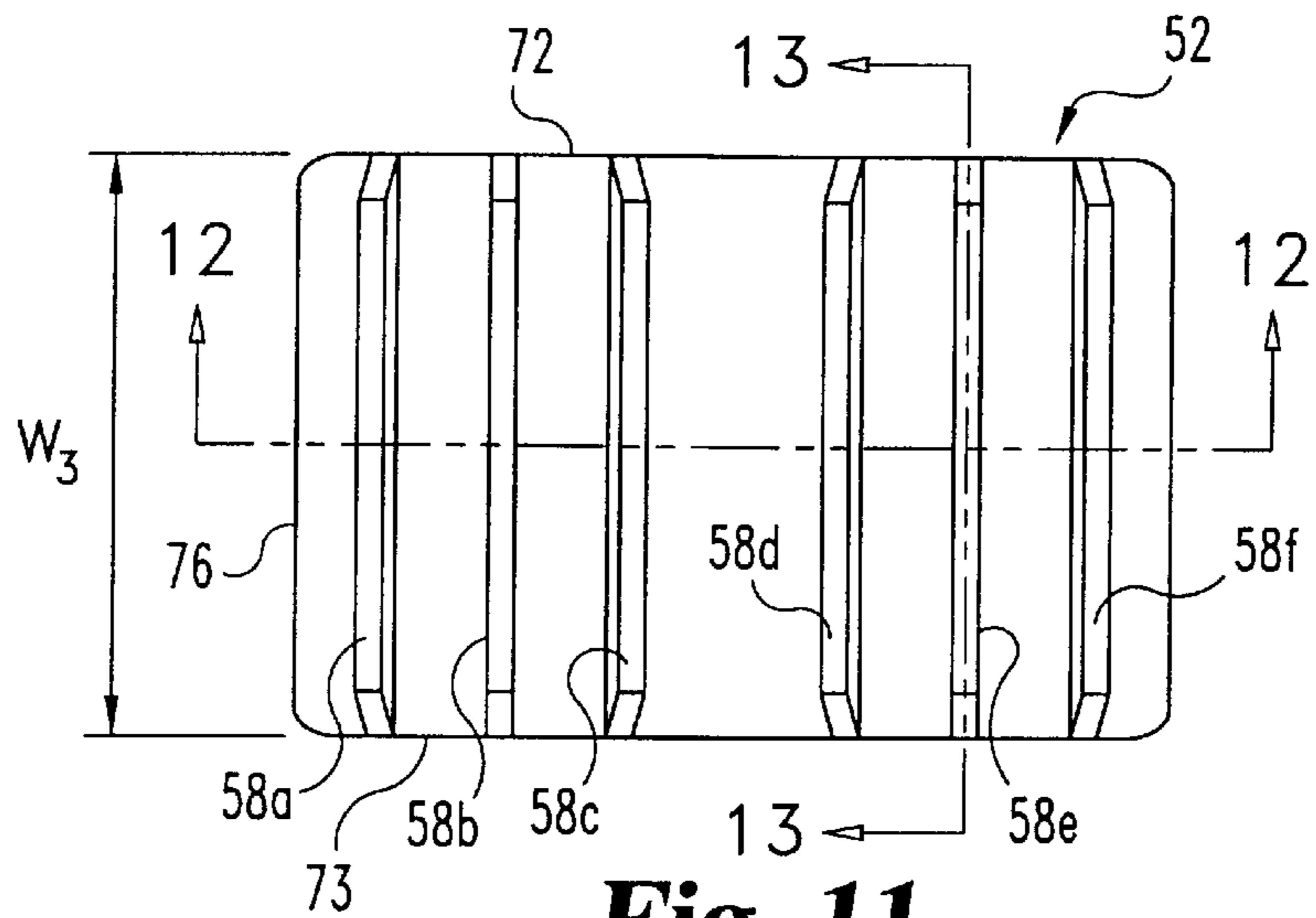


Fig. 11

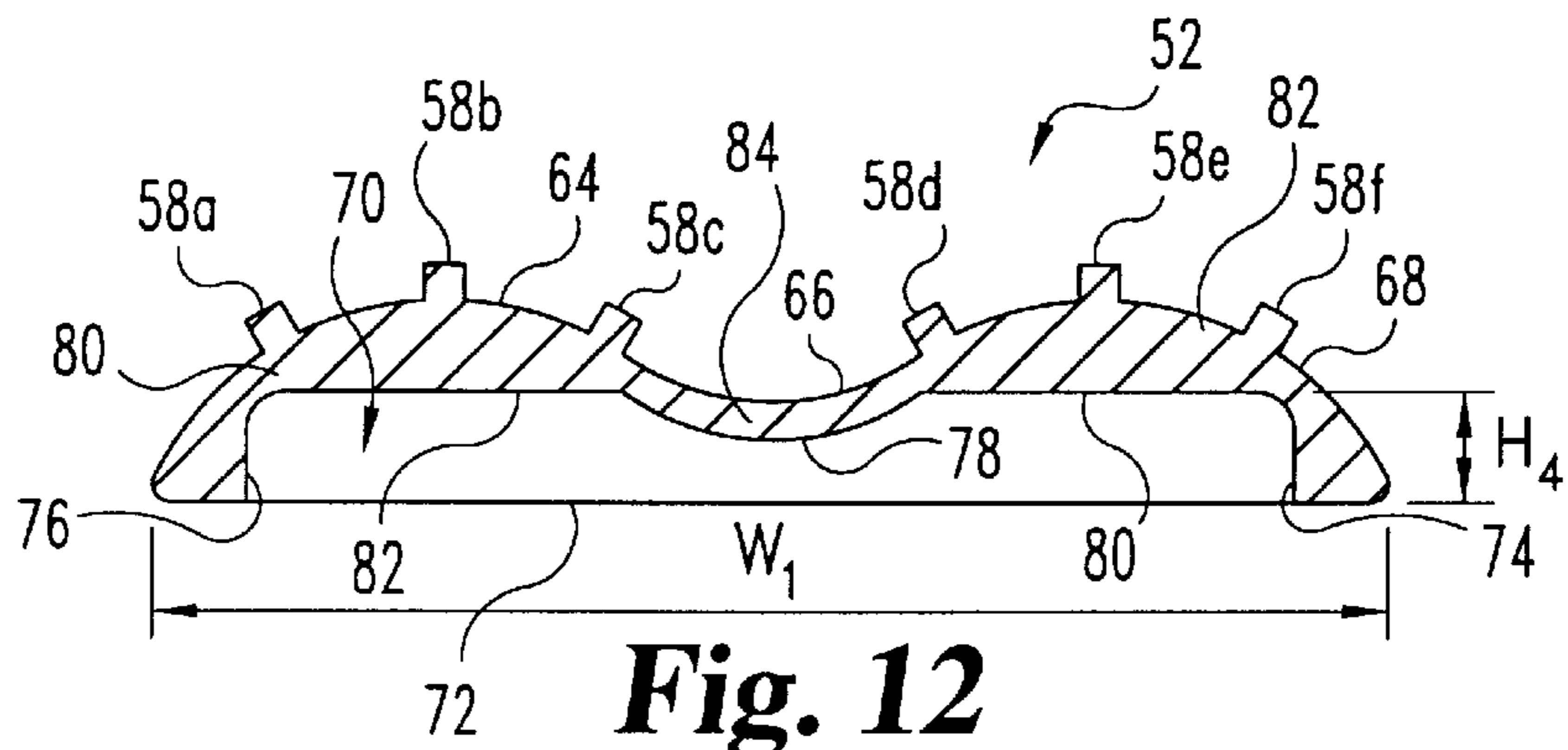


Fig. 12

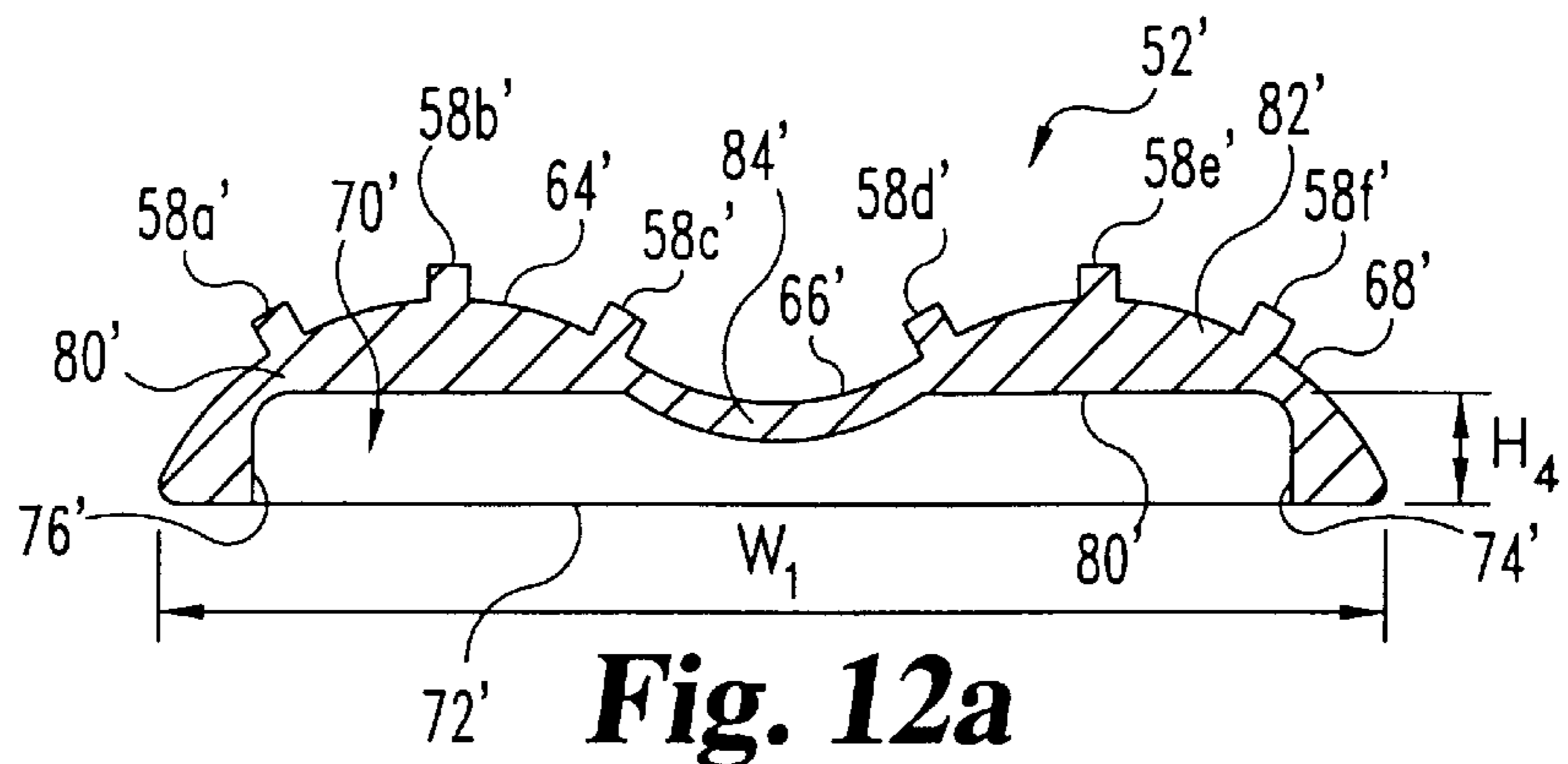


Fig. 12a

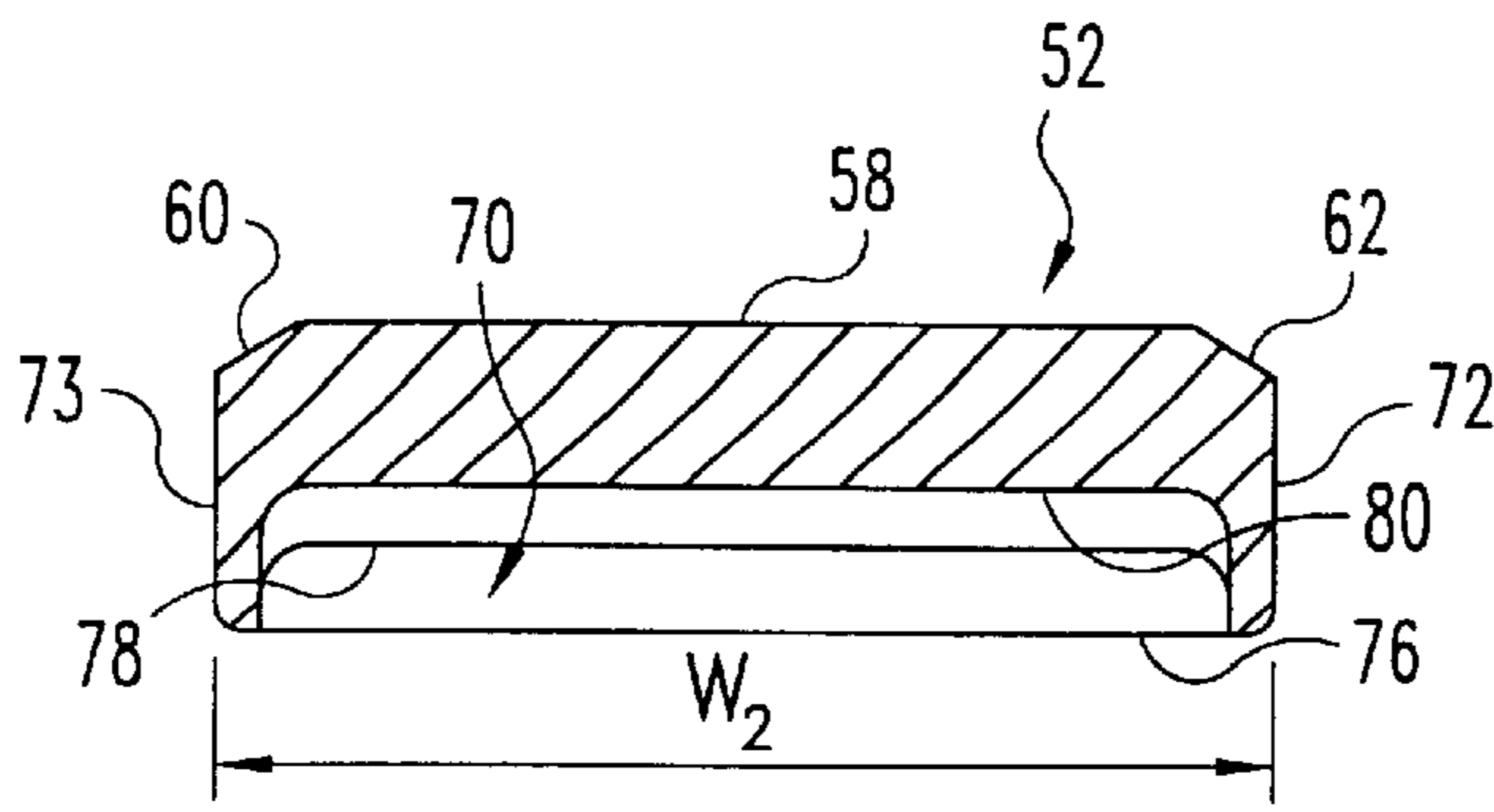


Fig. 13

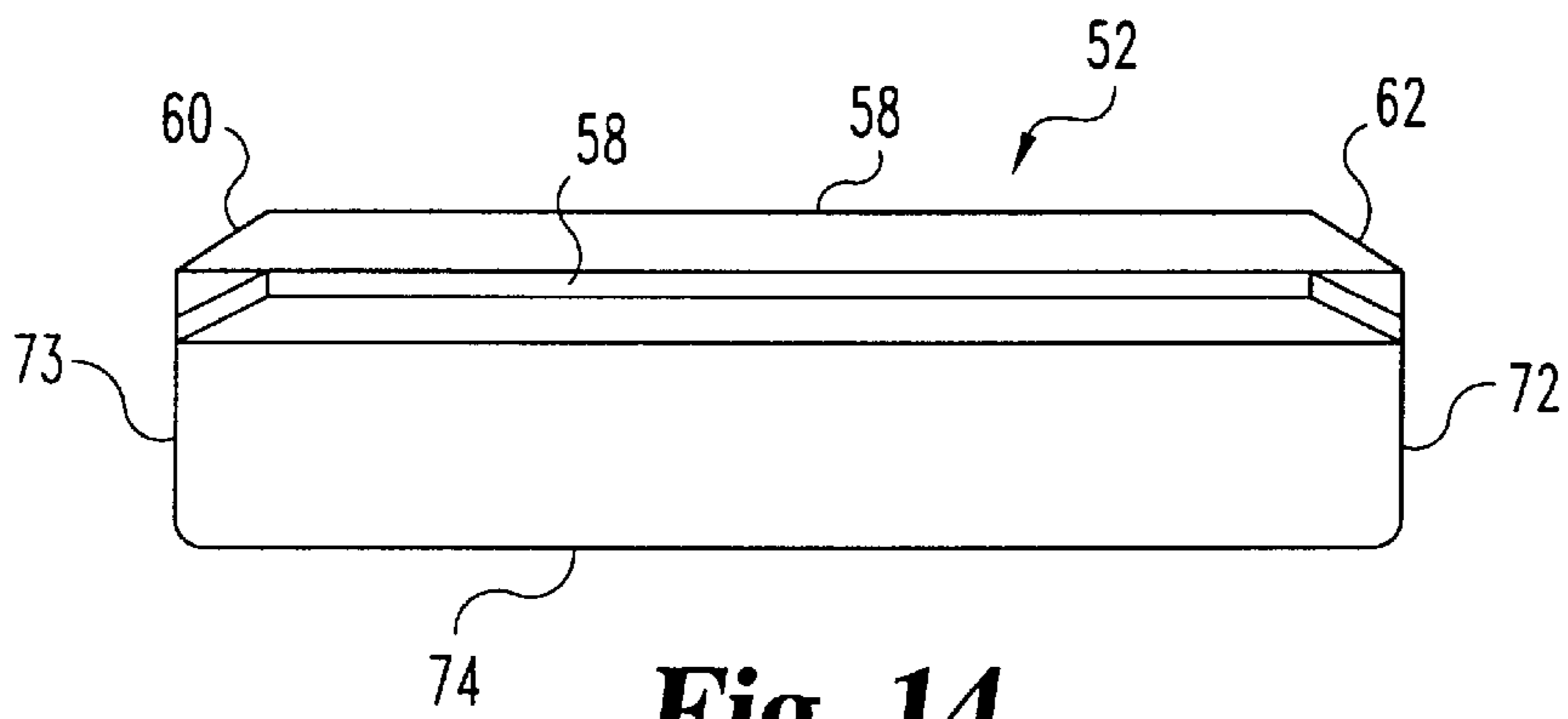


Fig. 14

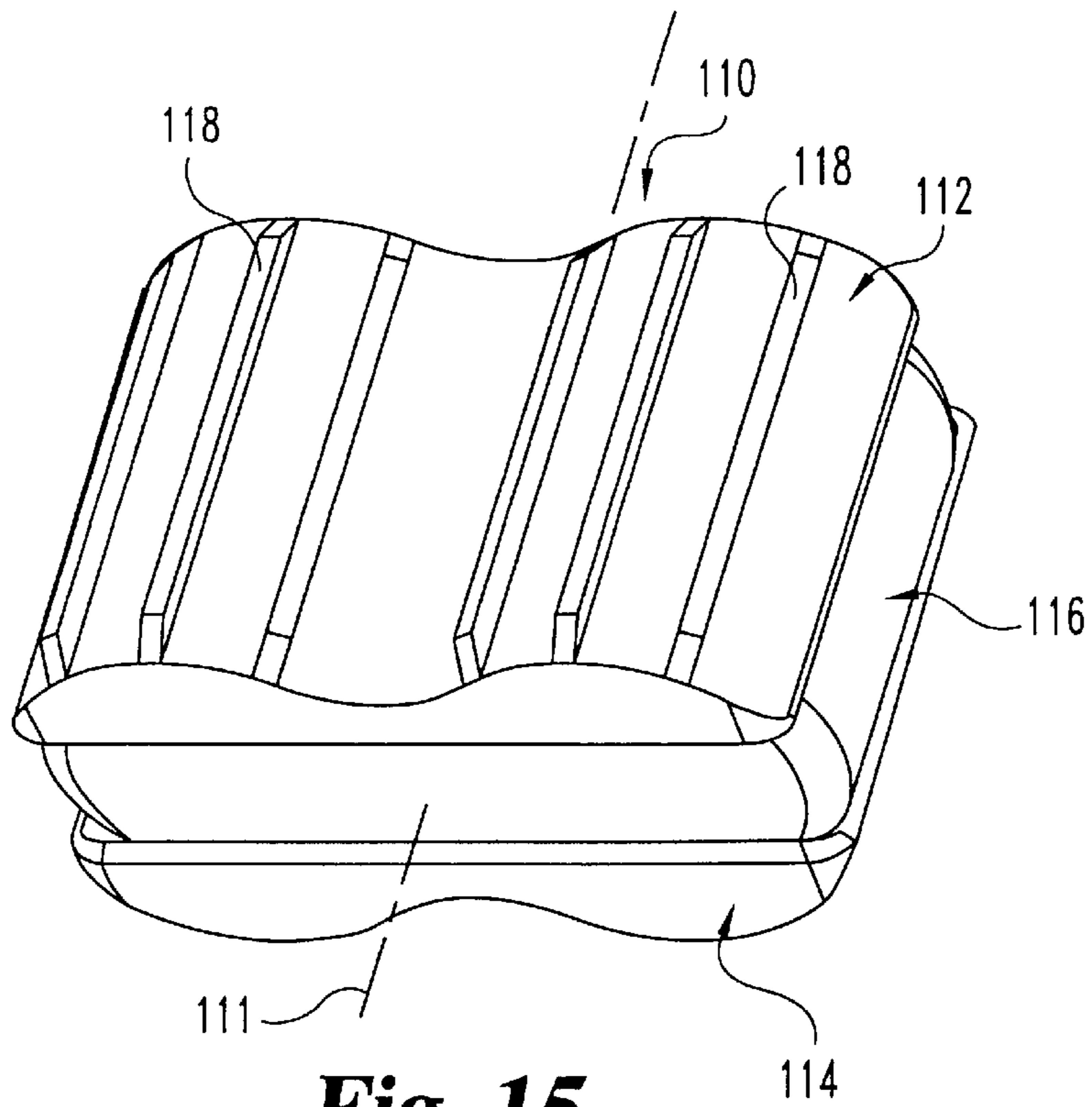


Fig. 15

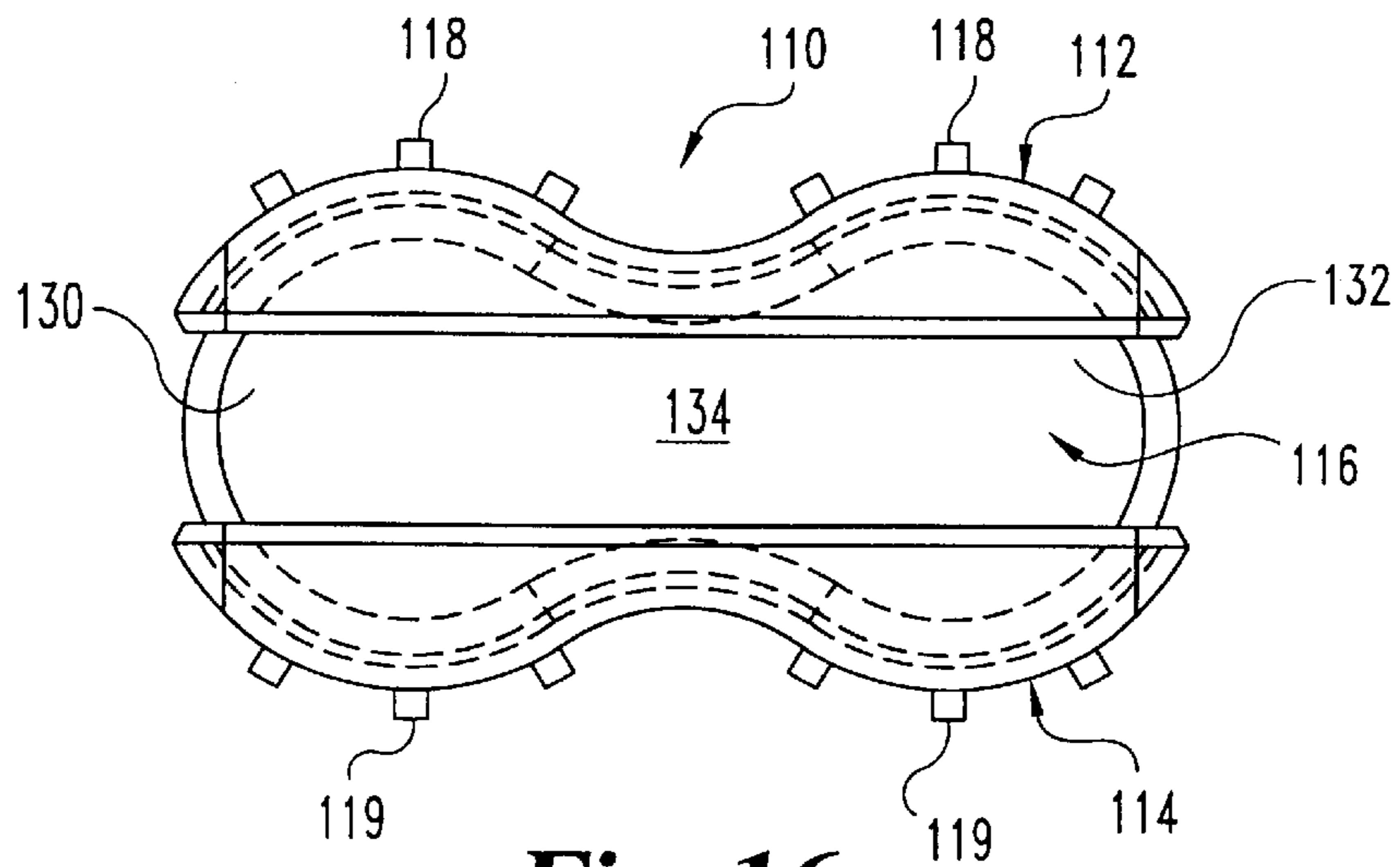


Fig. 16

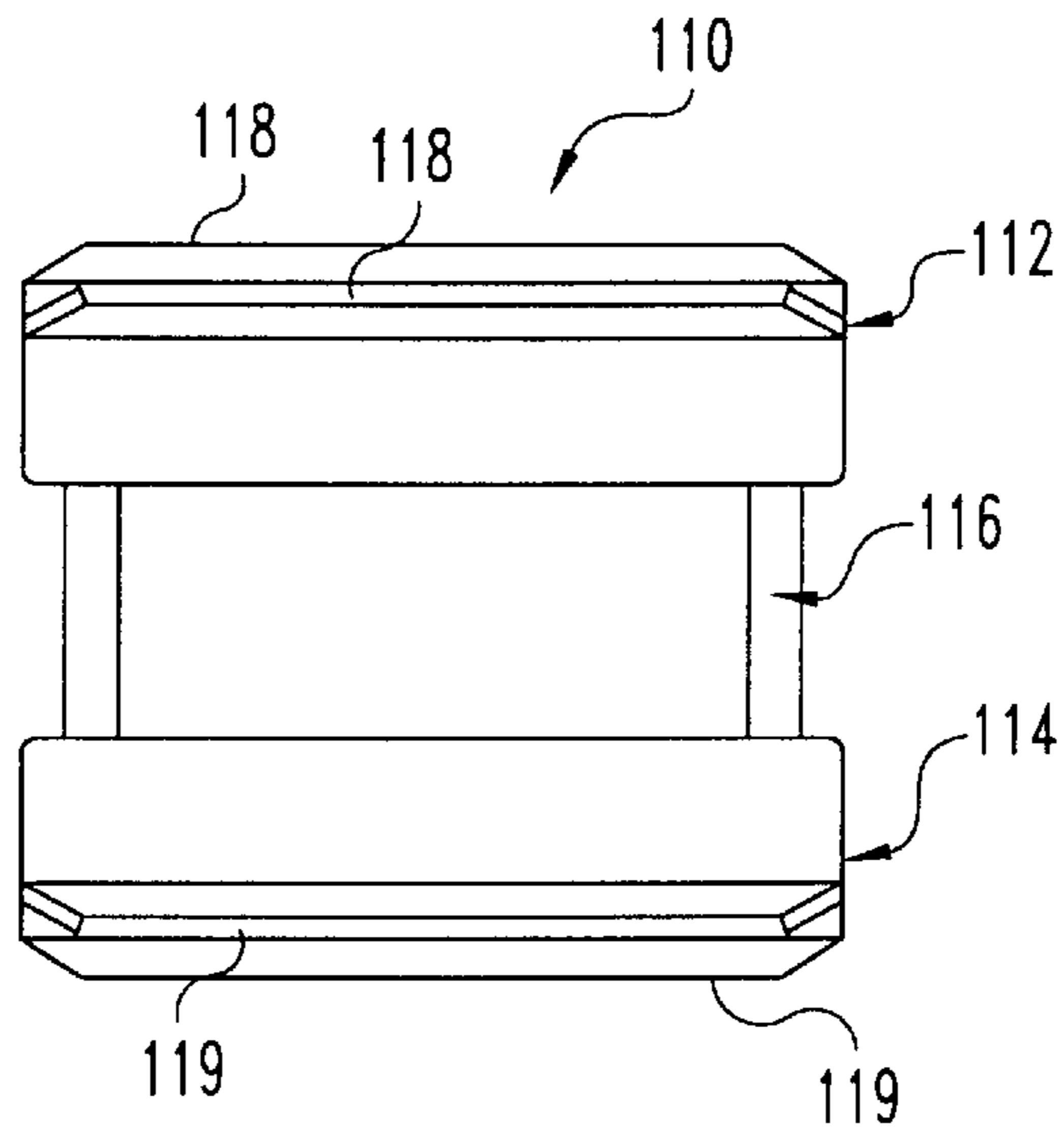


Fig. 17

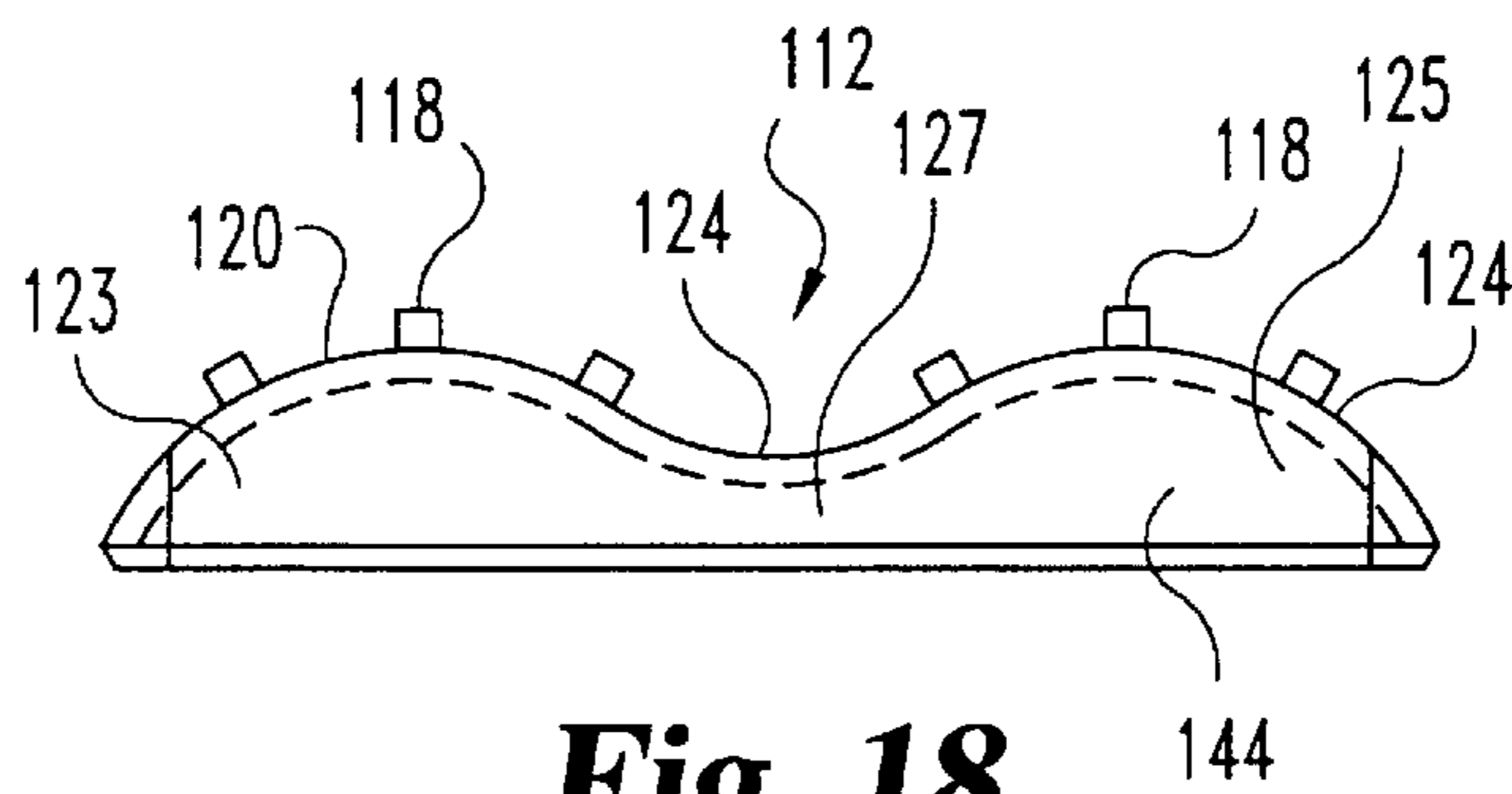


Fig. 18

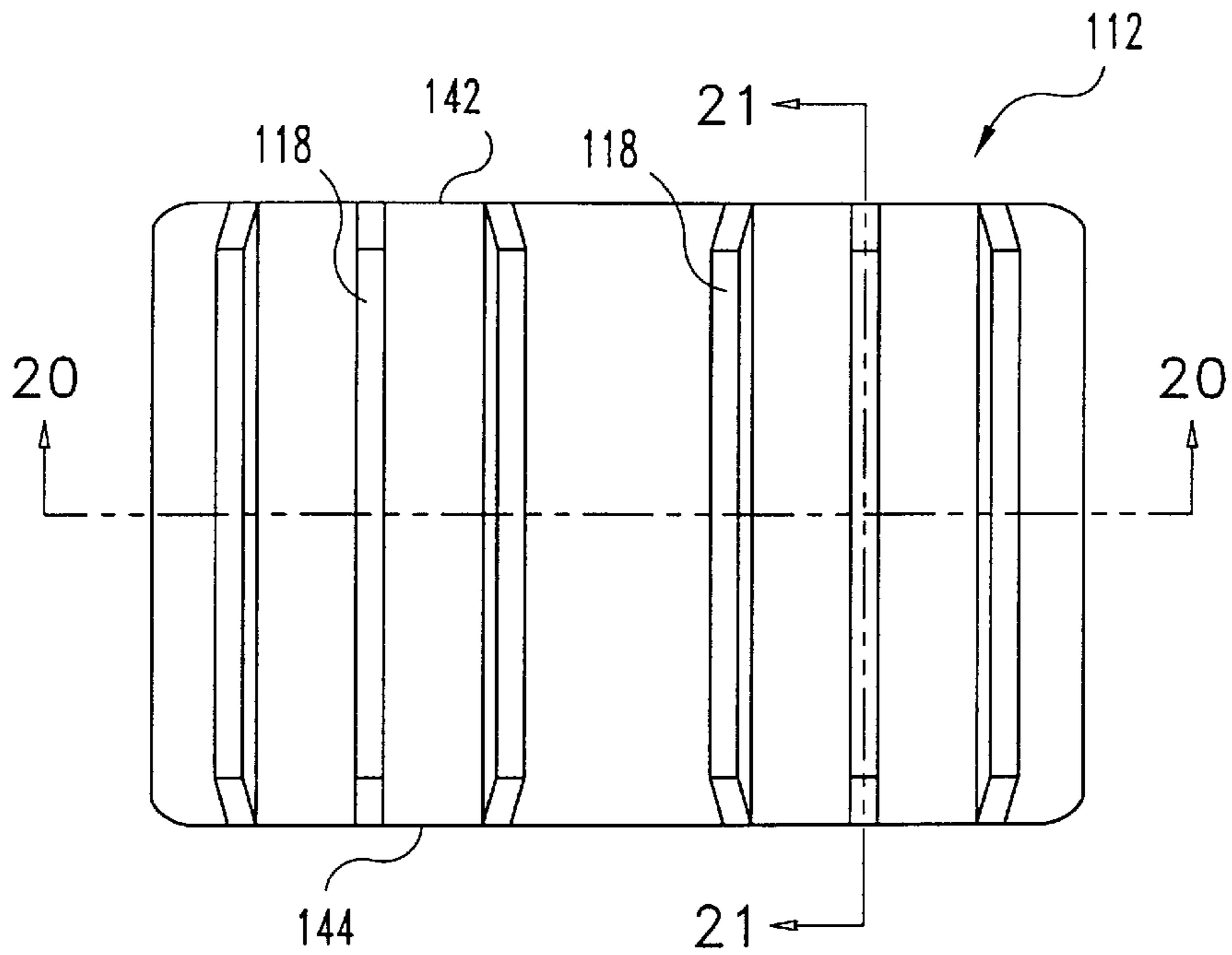


Fig. 19

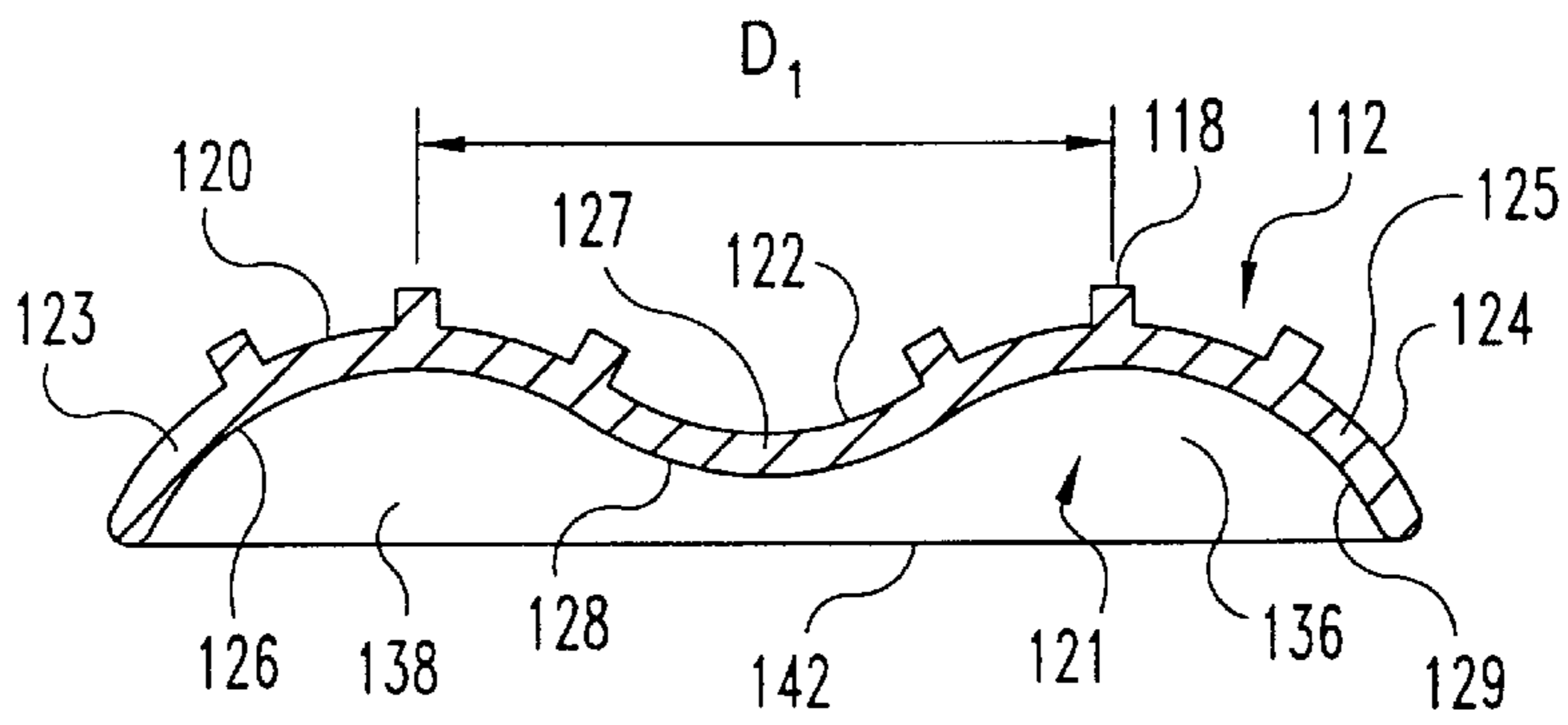


Fig. 20

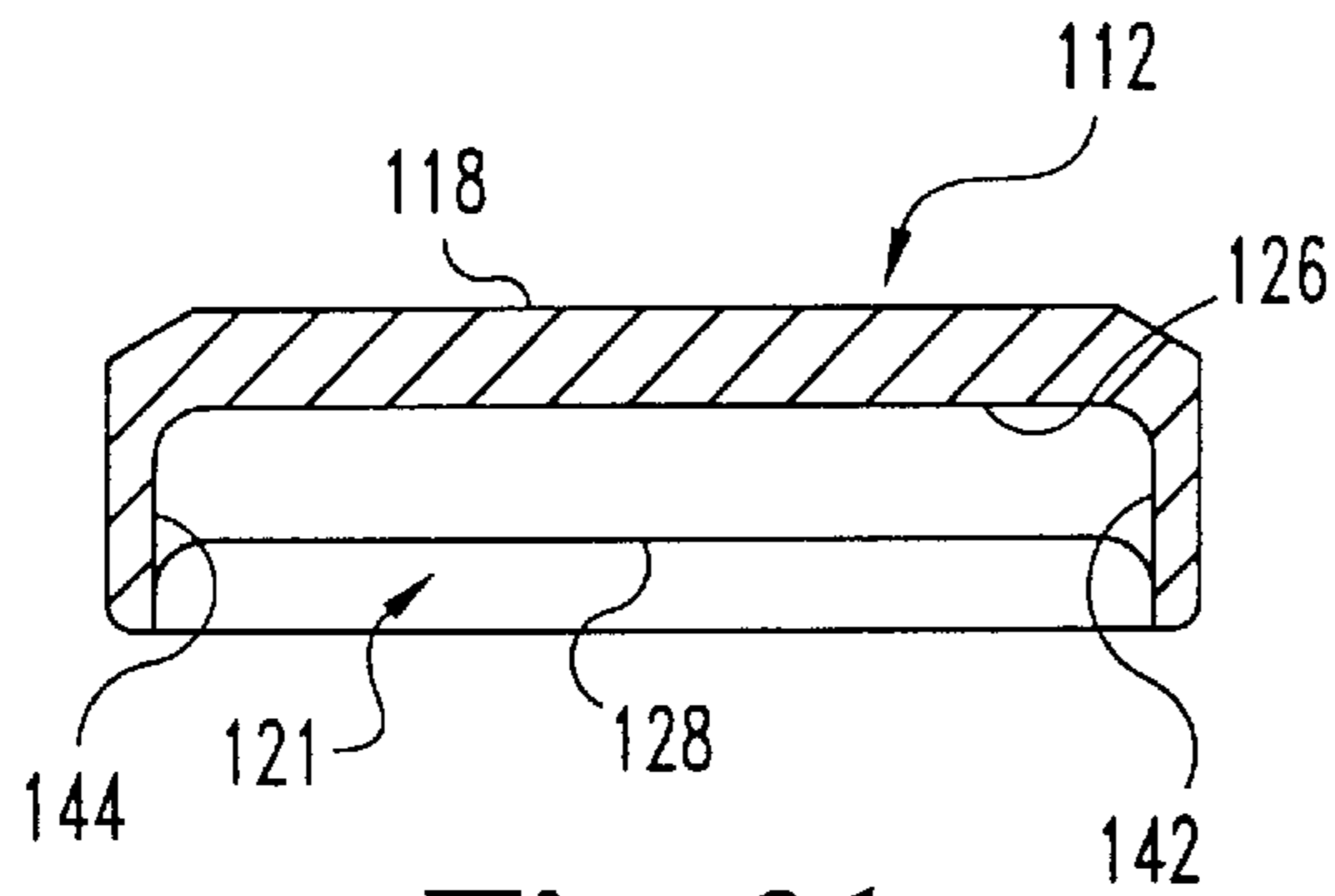


Fig. 21

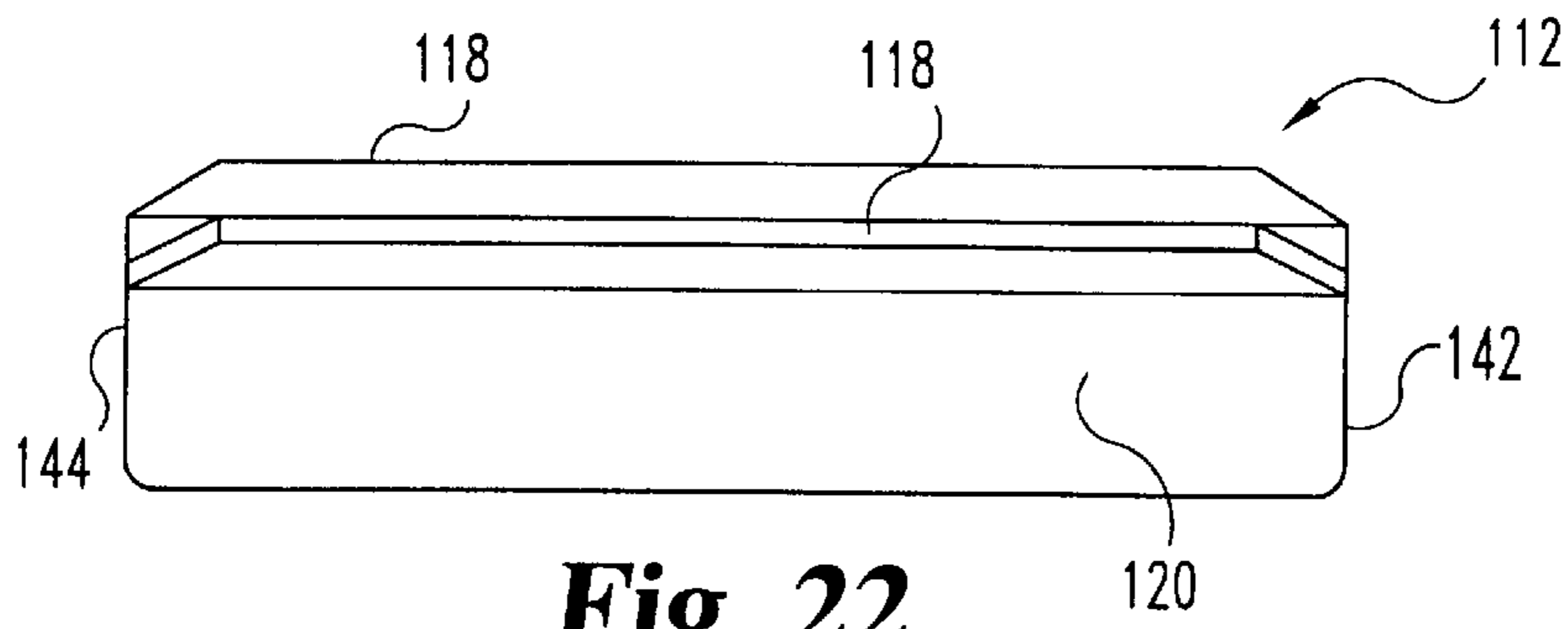


Fig. 22

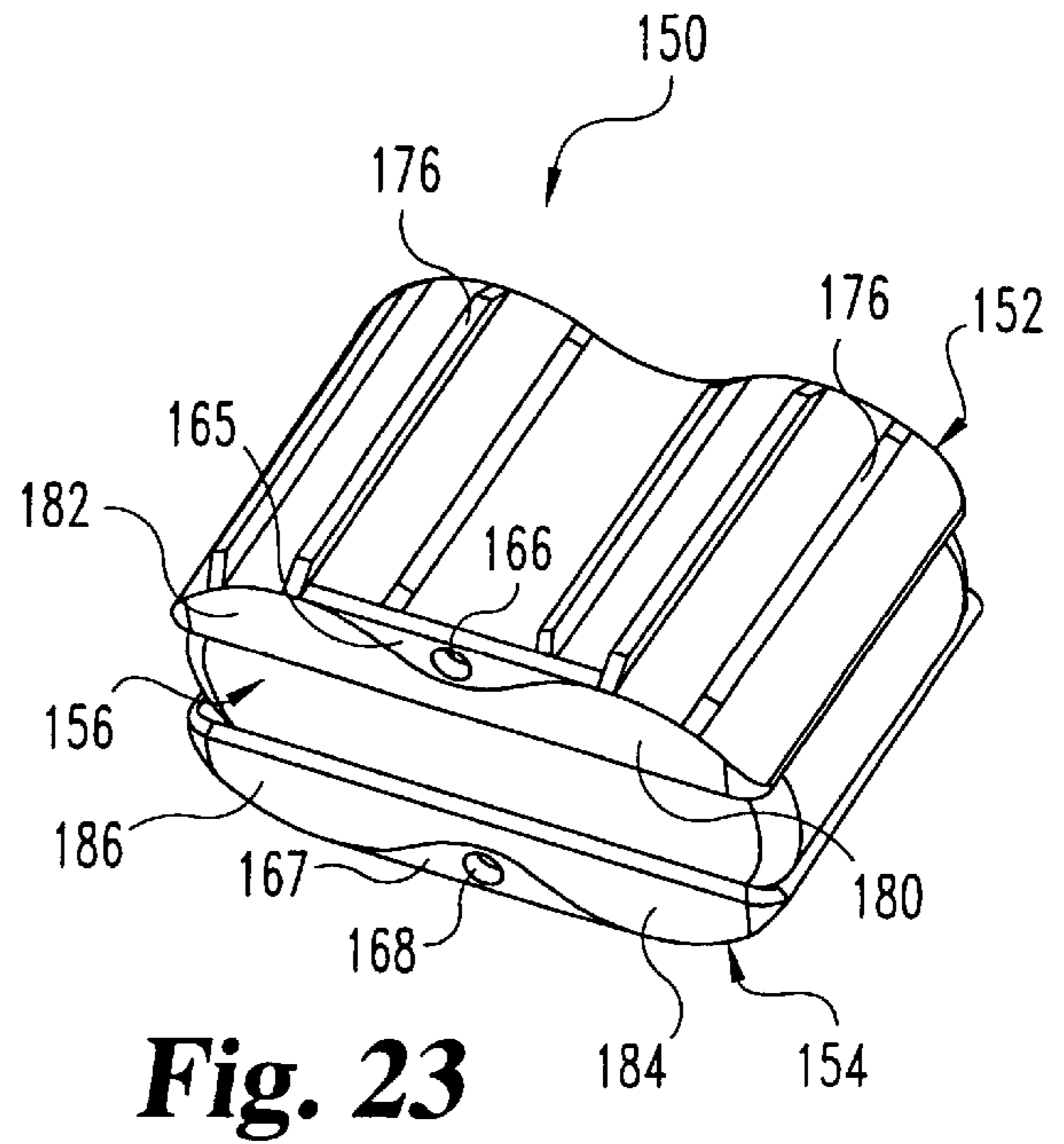


Fig. 23

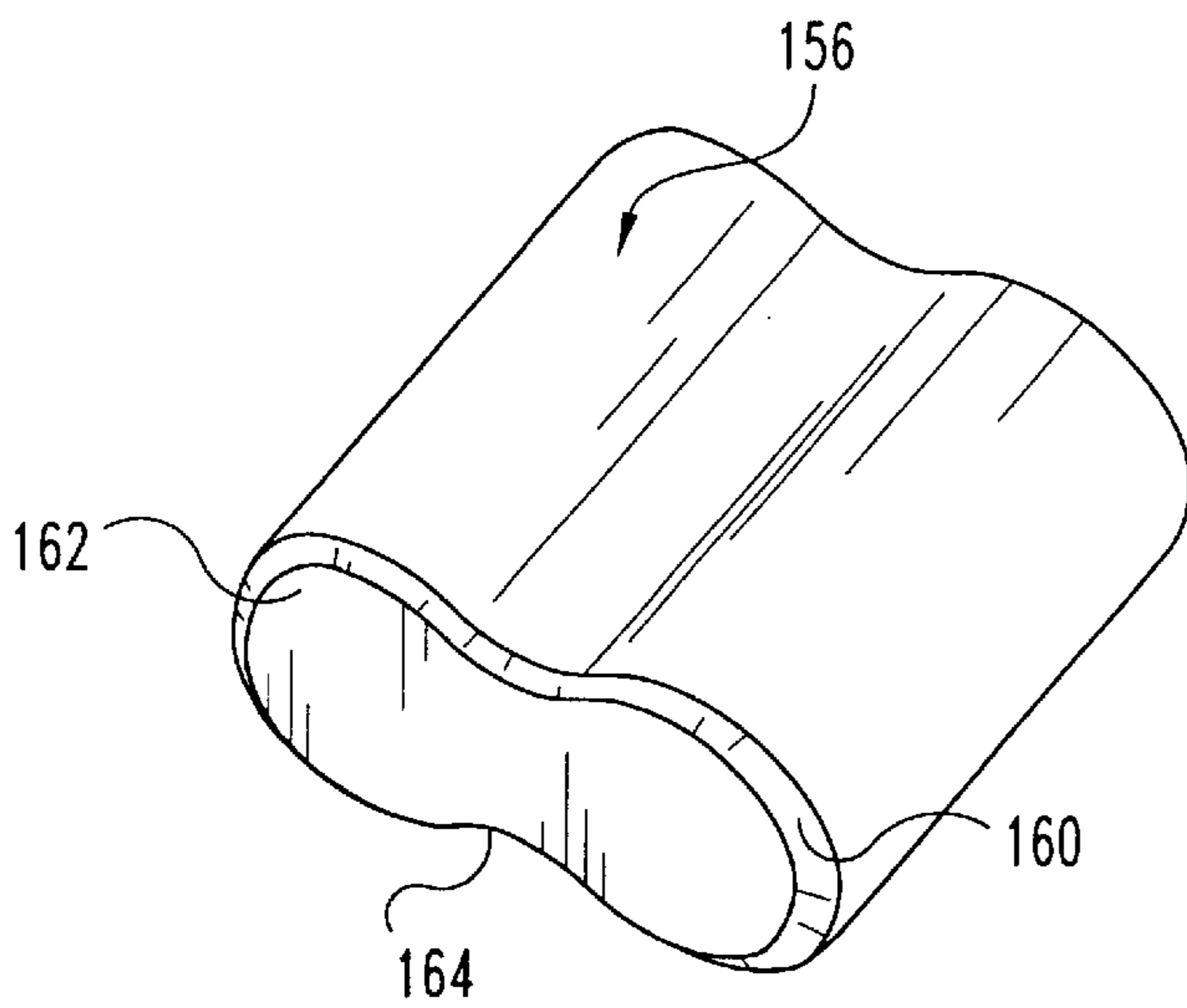


Fig. 24

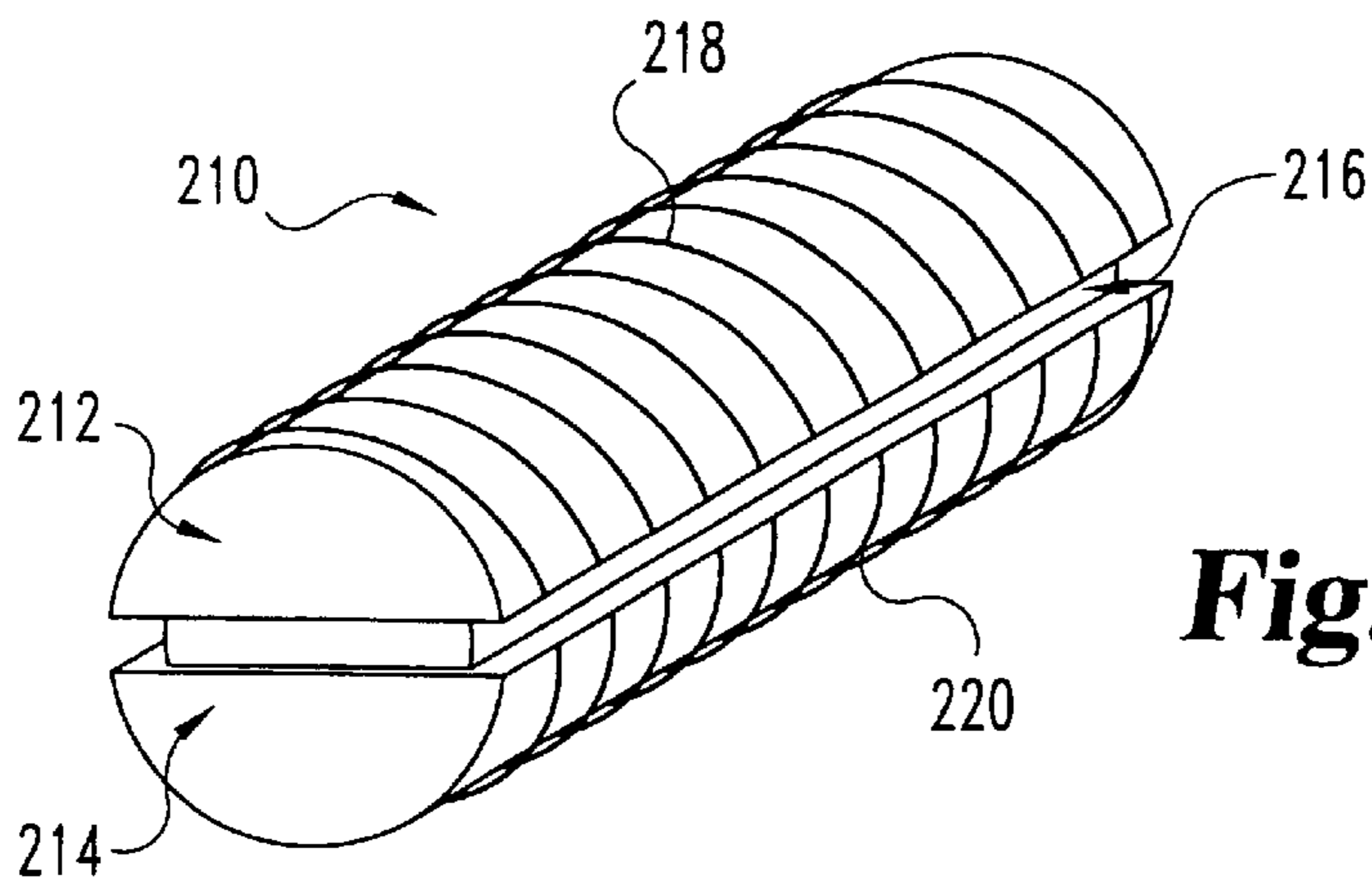


Fig. 28

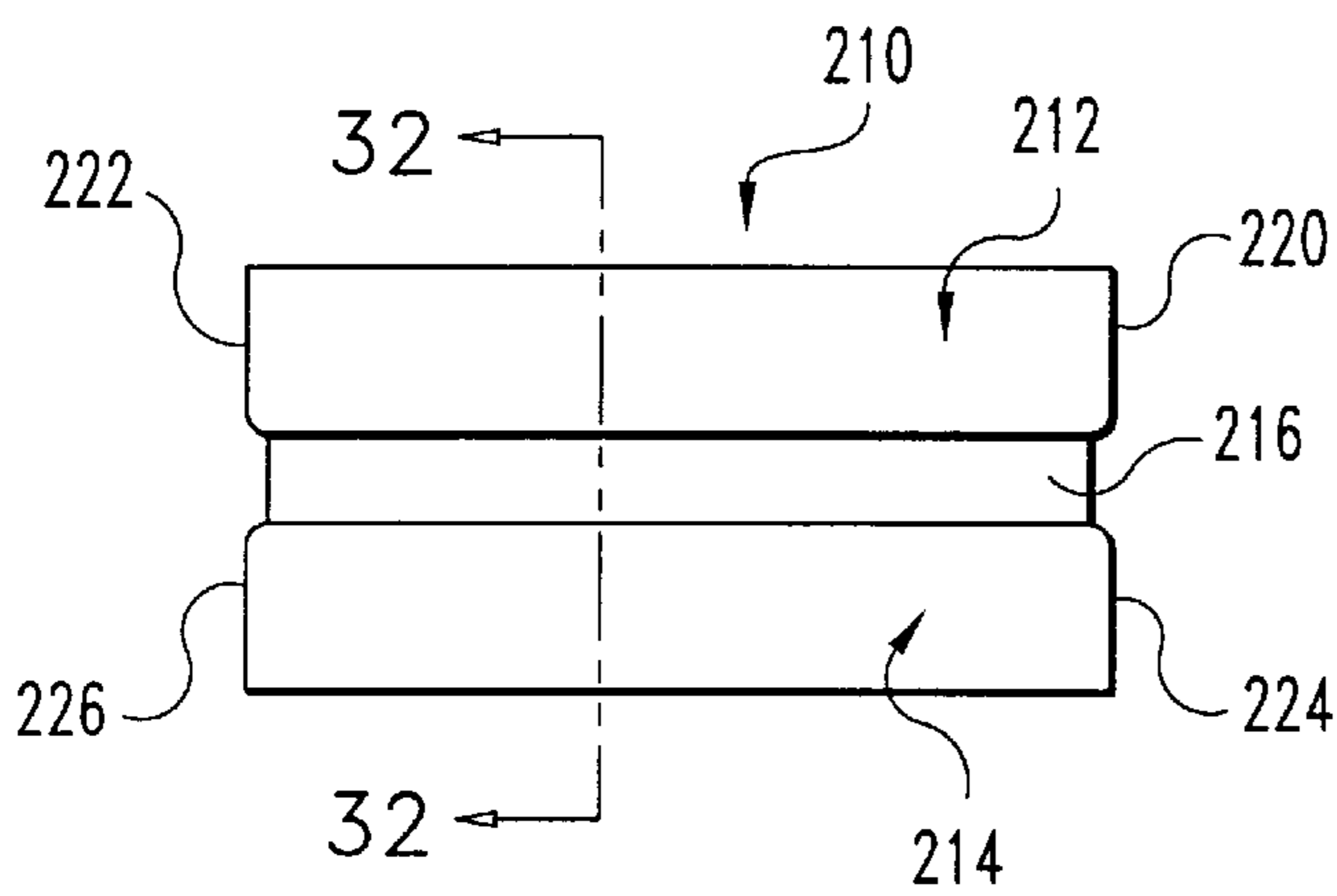


Fig. 29

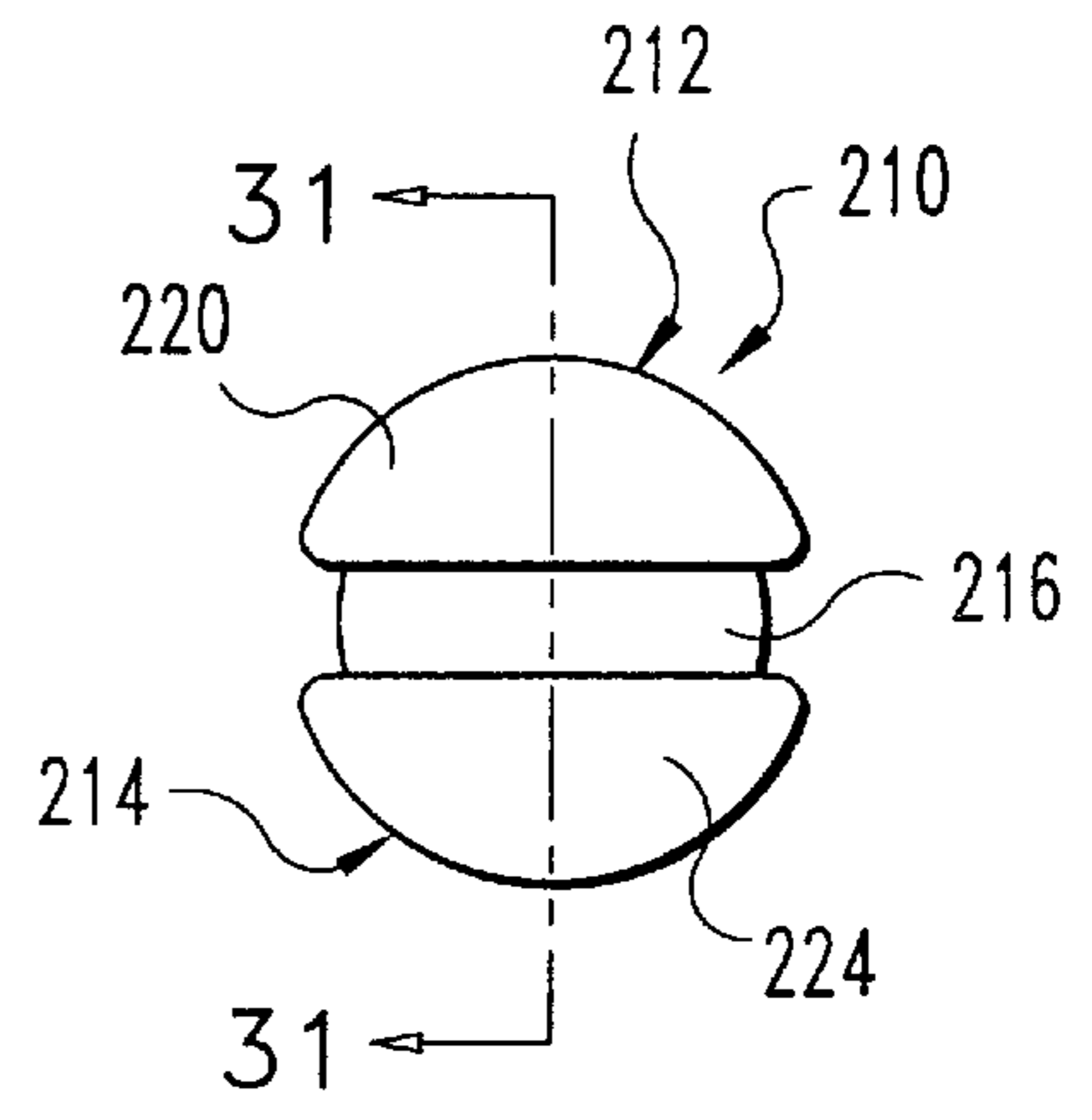


Fig. 30

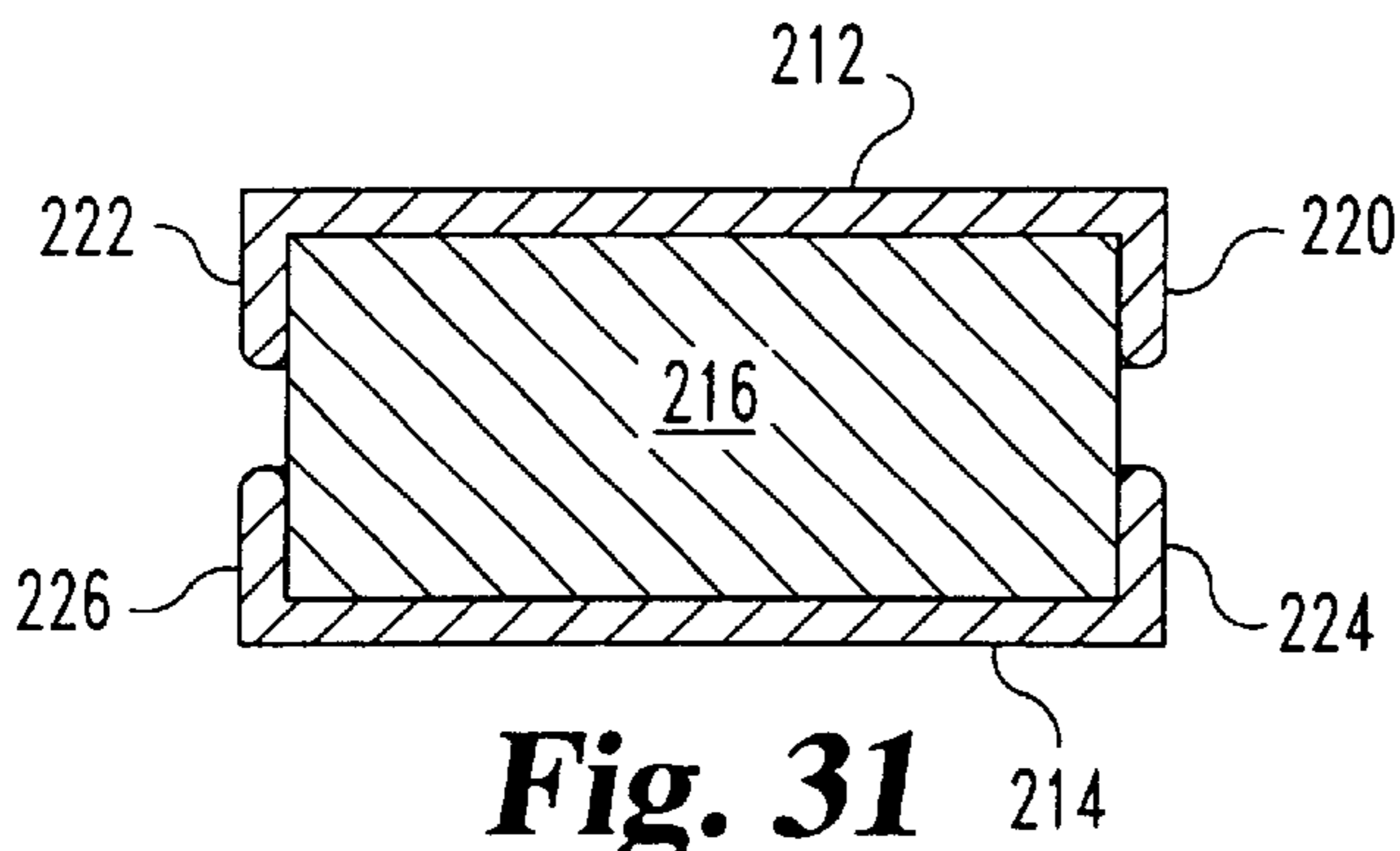


Fig. 31

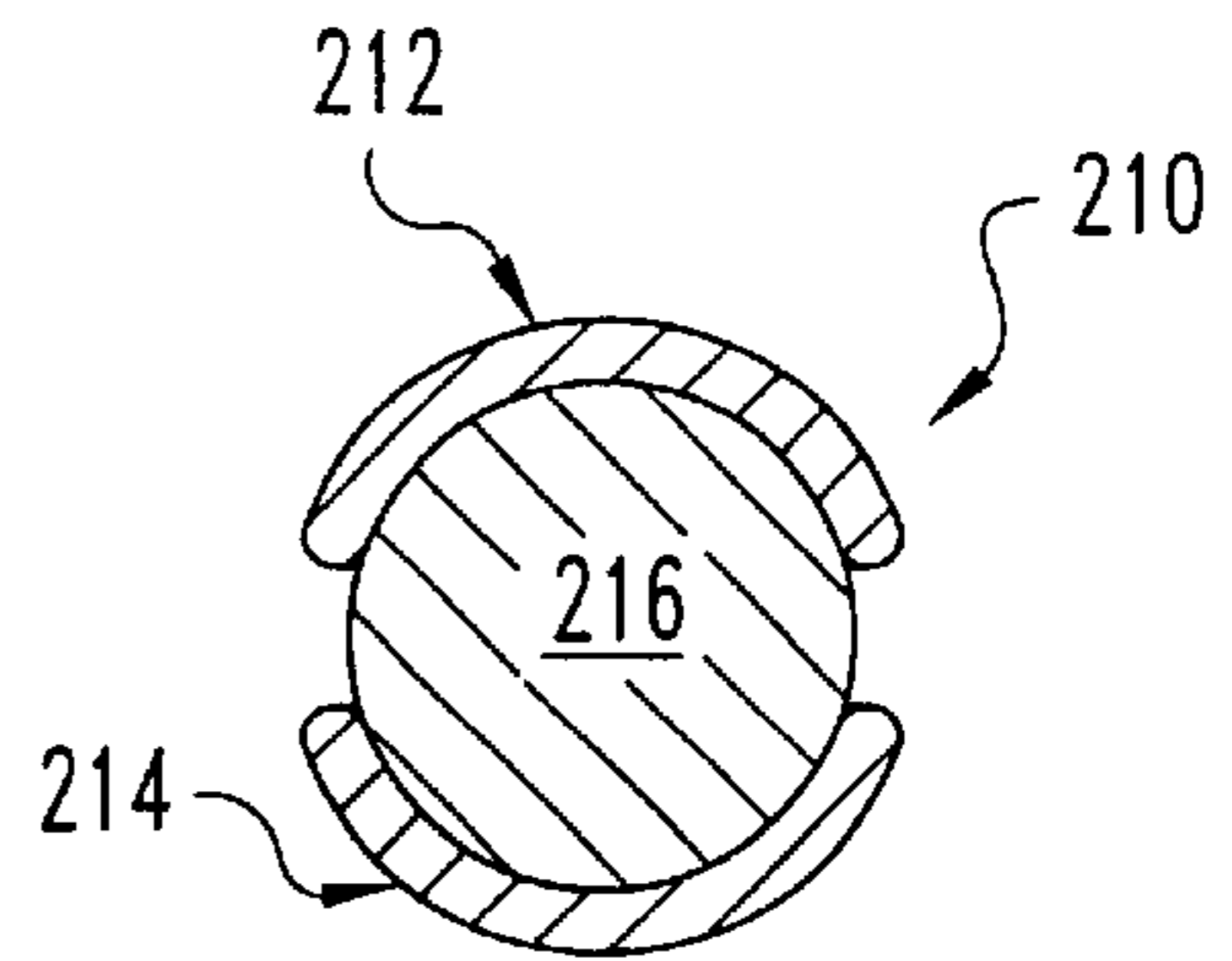


Fig. 32

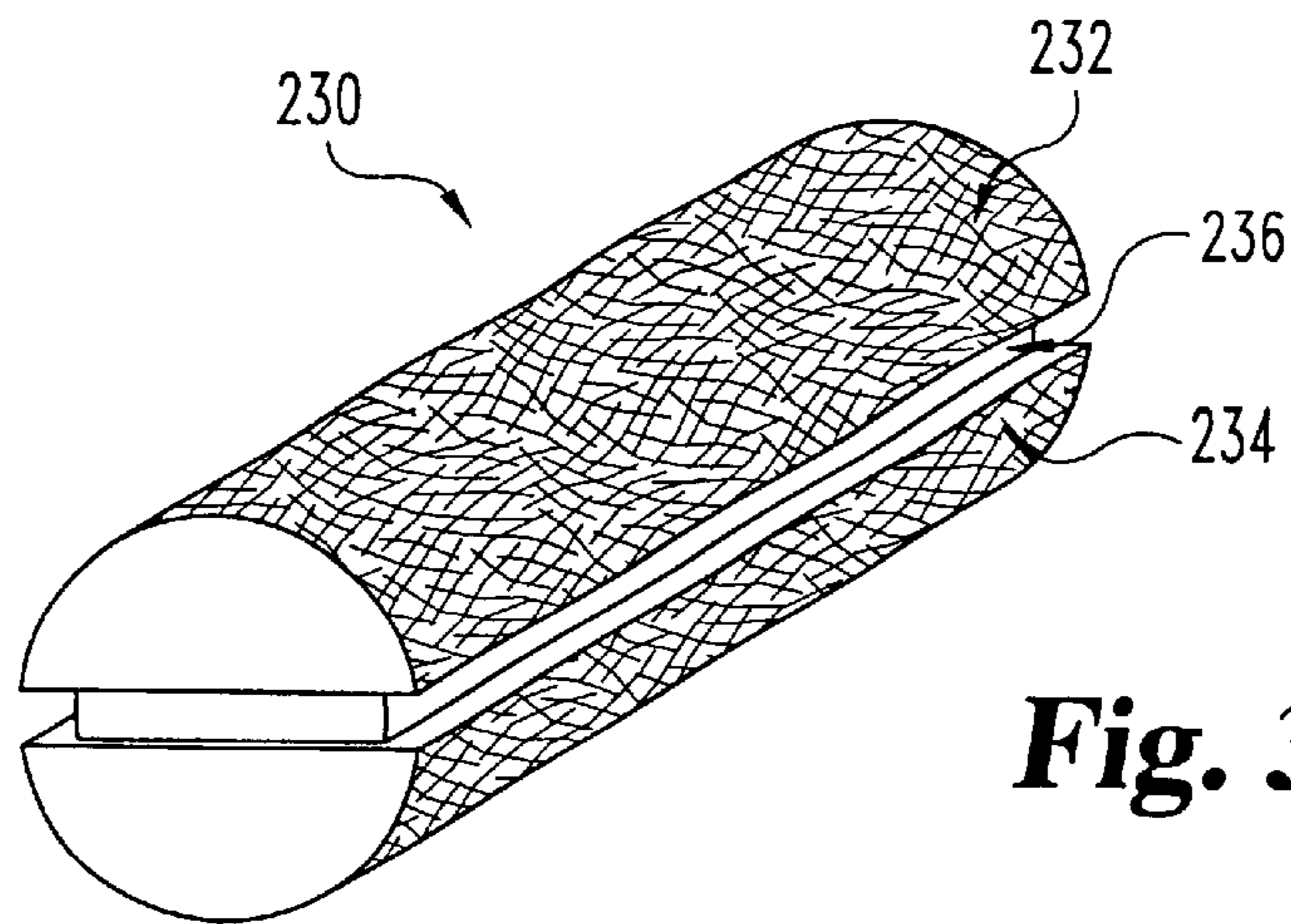


Fig. 33

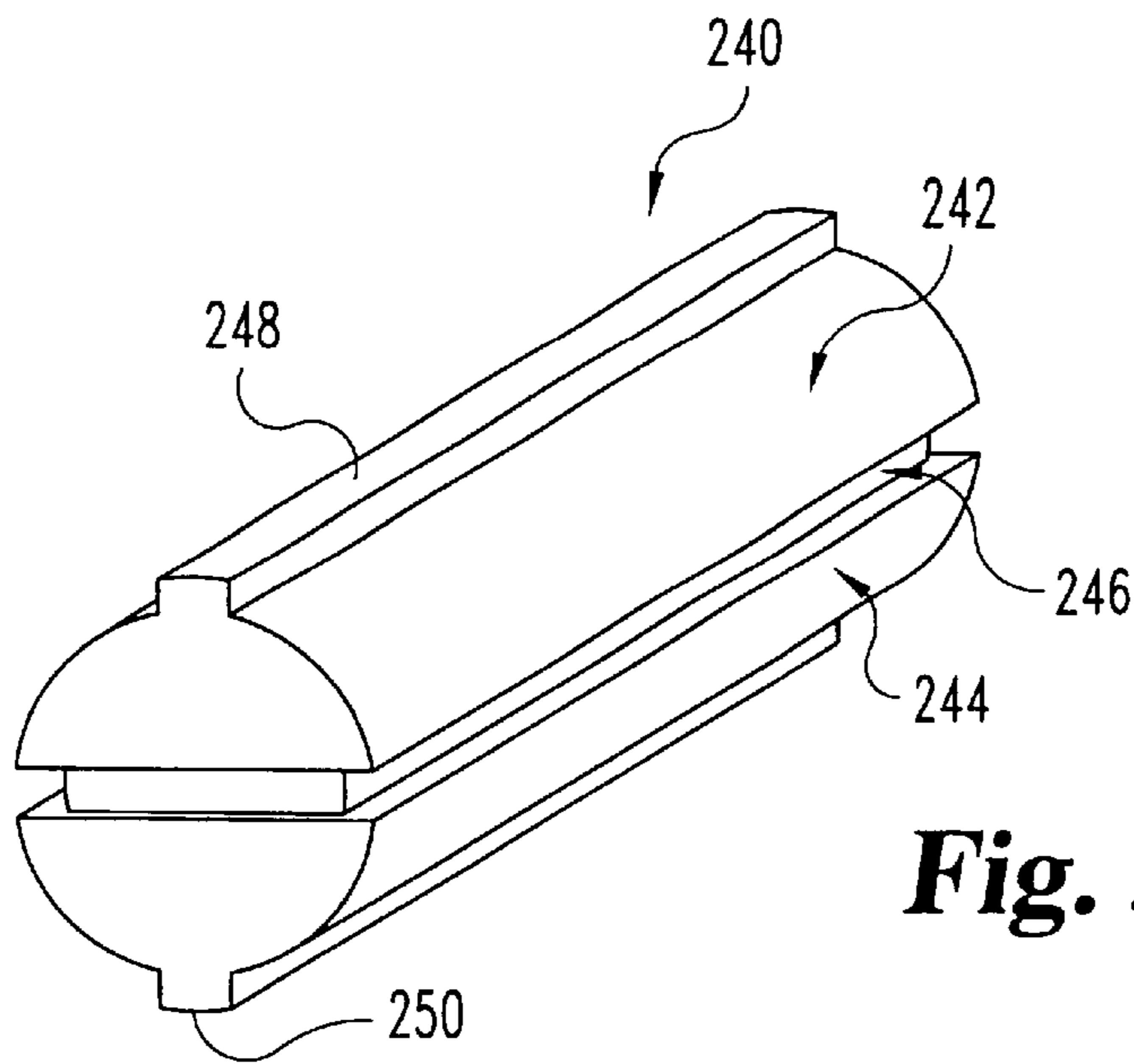


Fig. 34

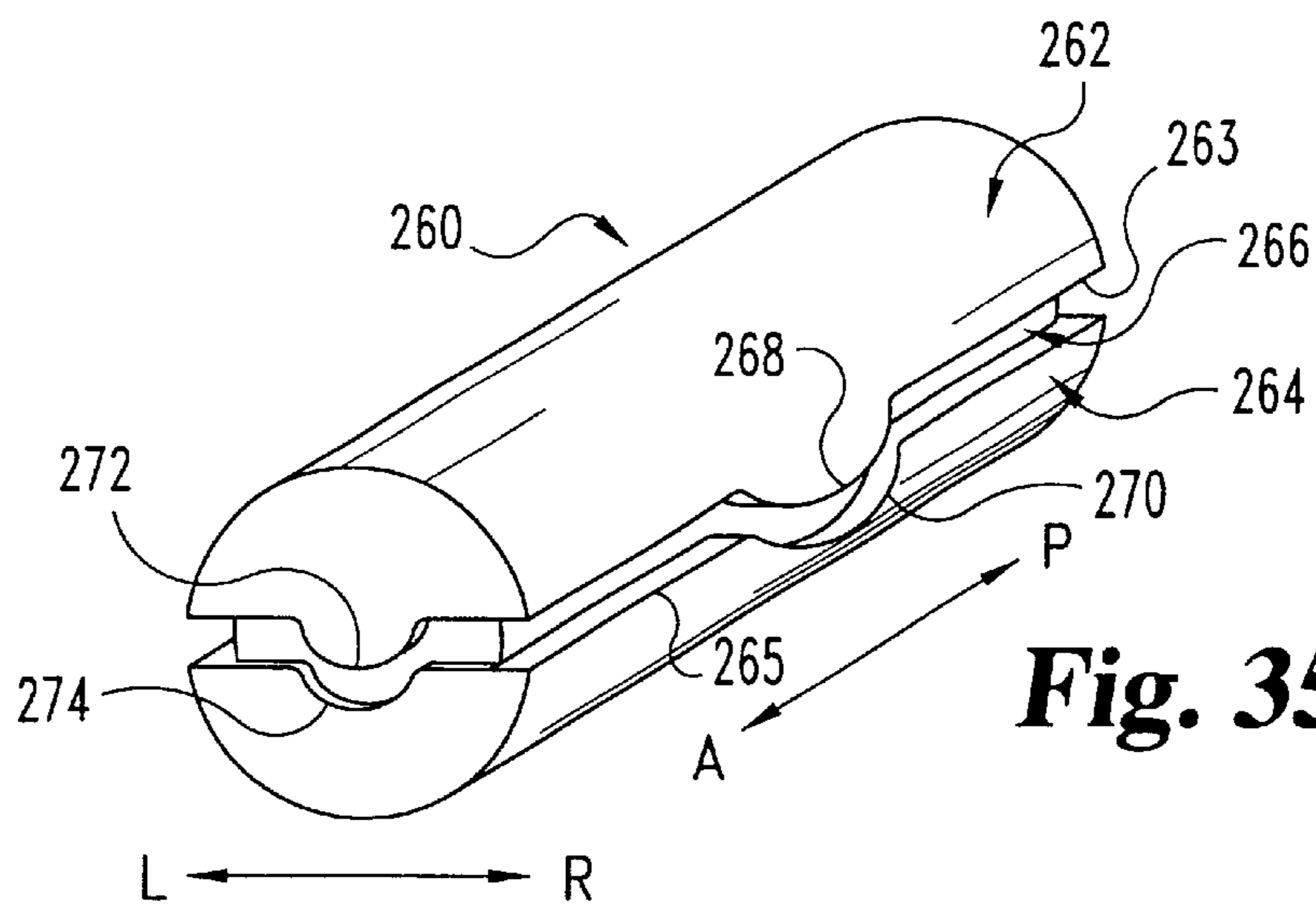


Fig. 35

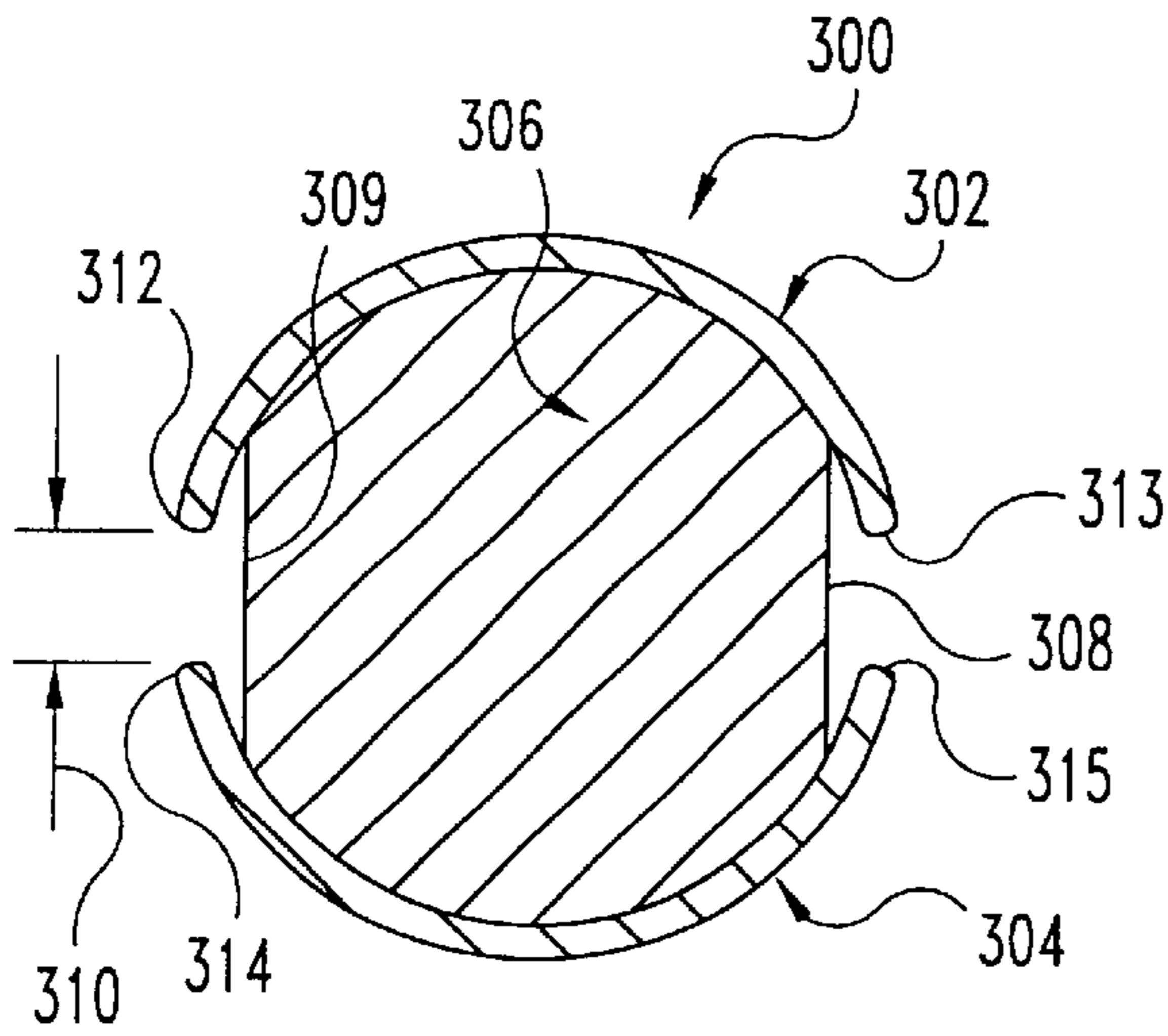


Fig. 36a

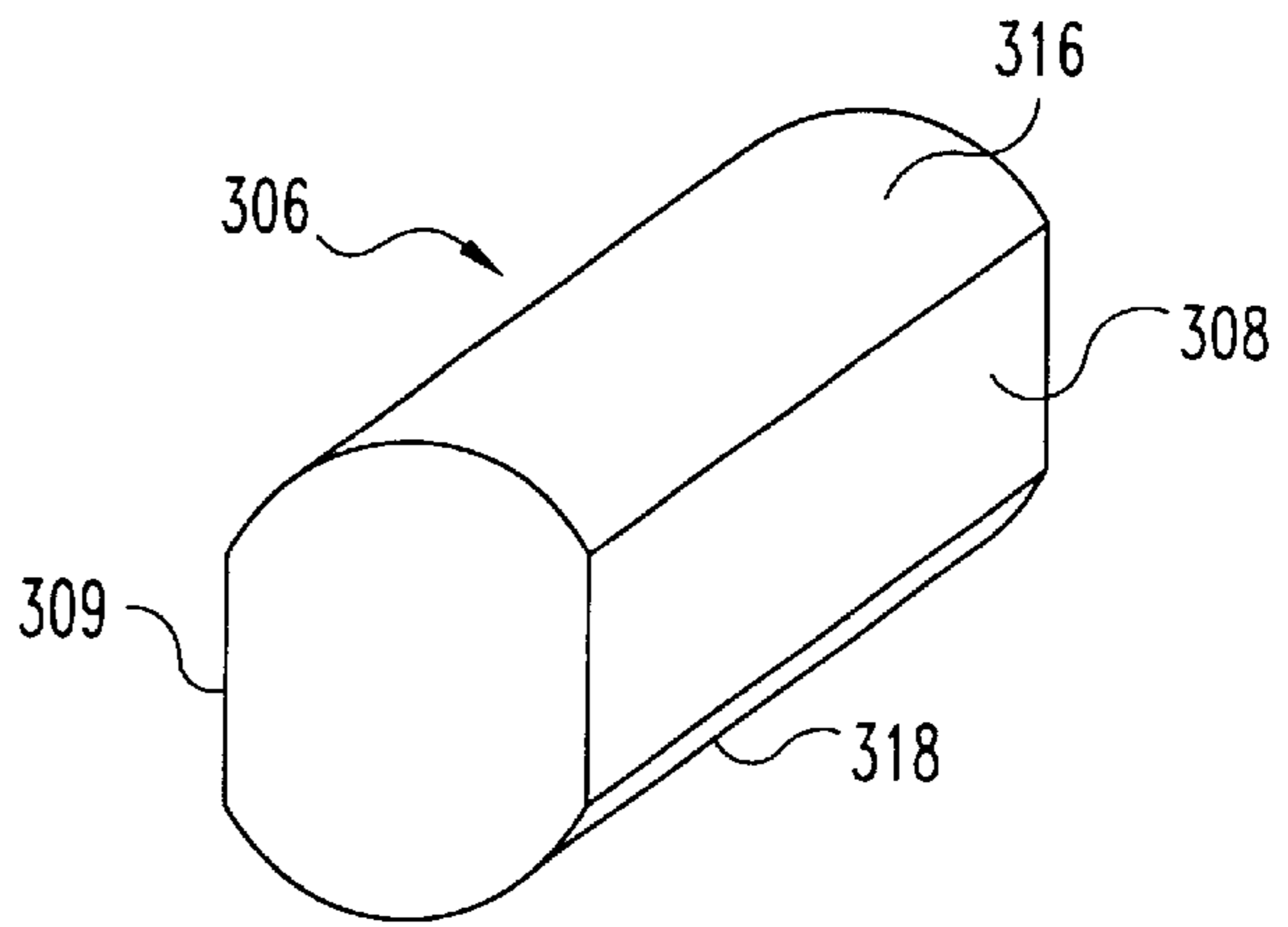


Fig. 36b

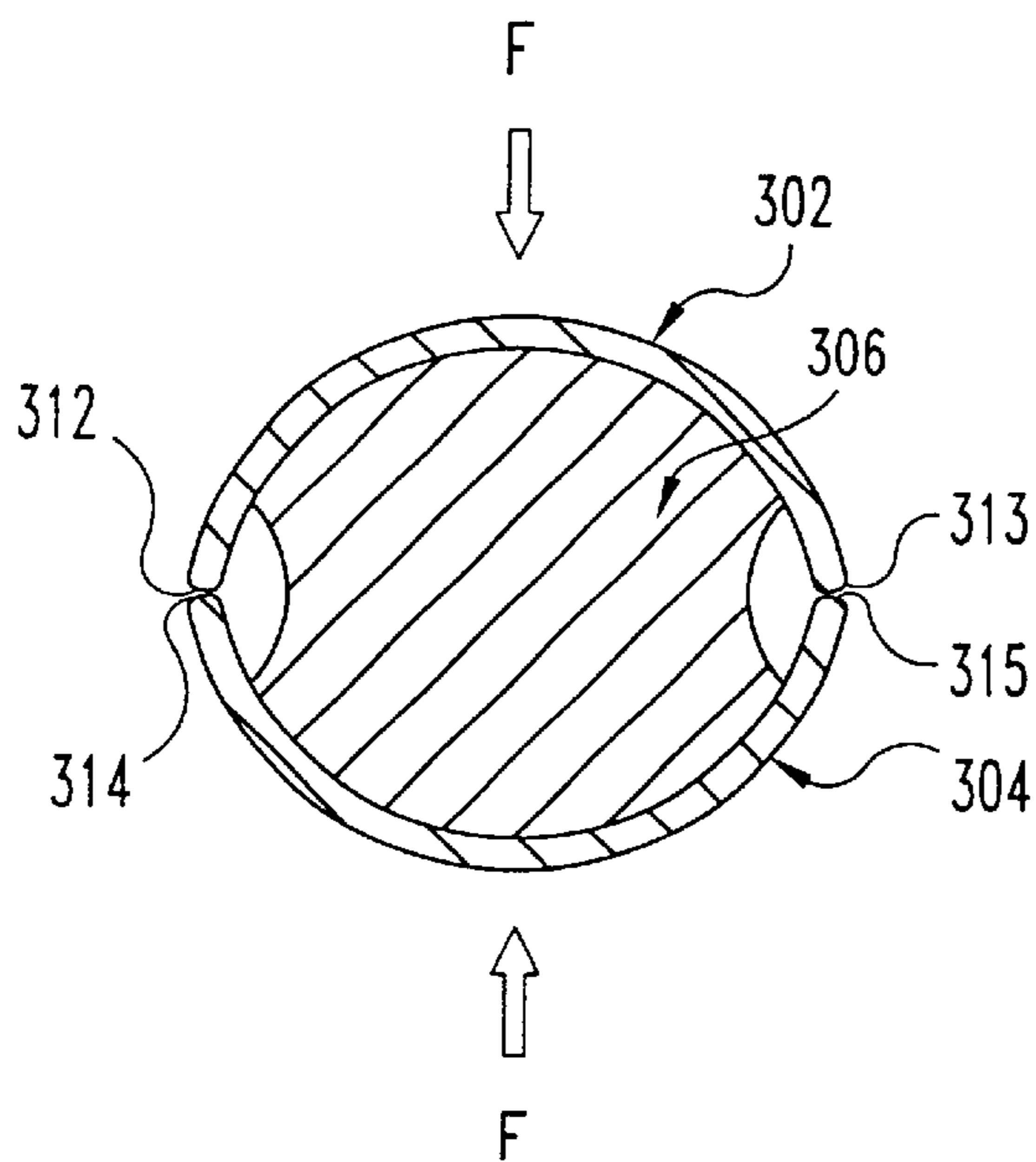


Fig. 37

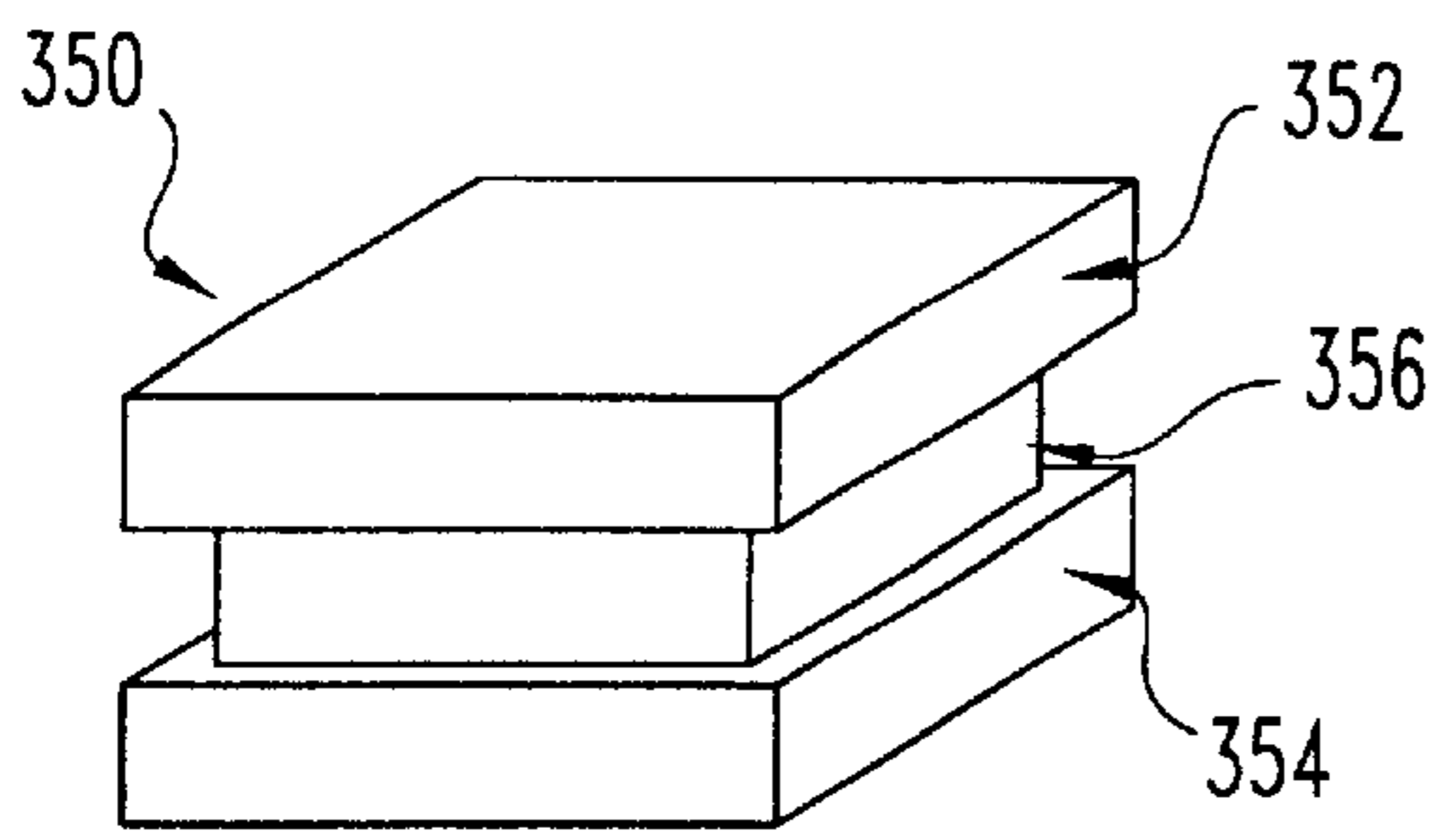


Fig. 38

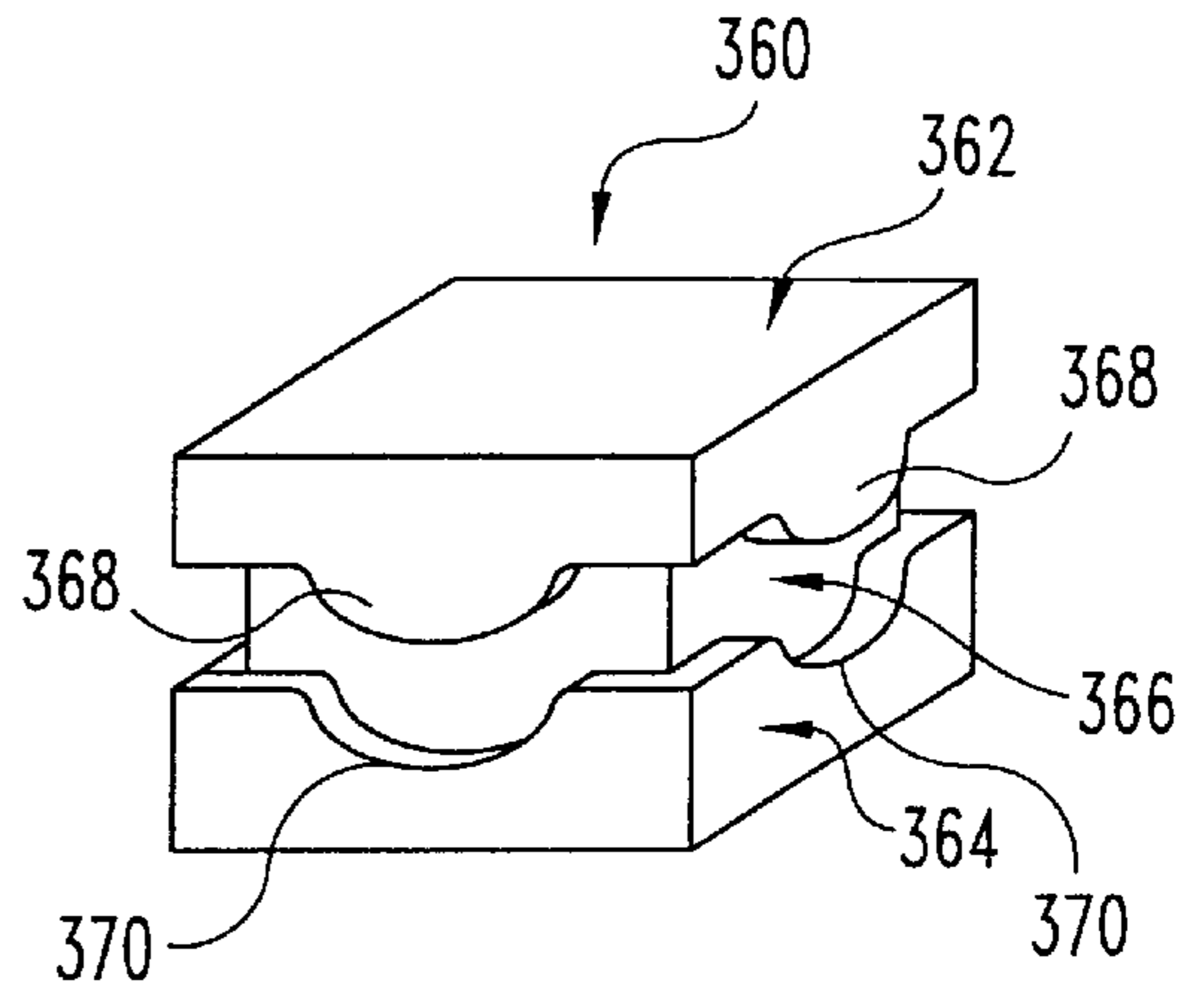


Fig. 39

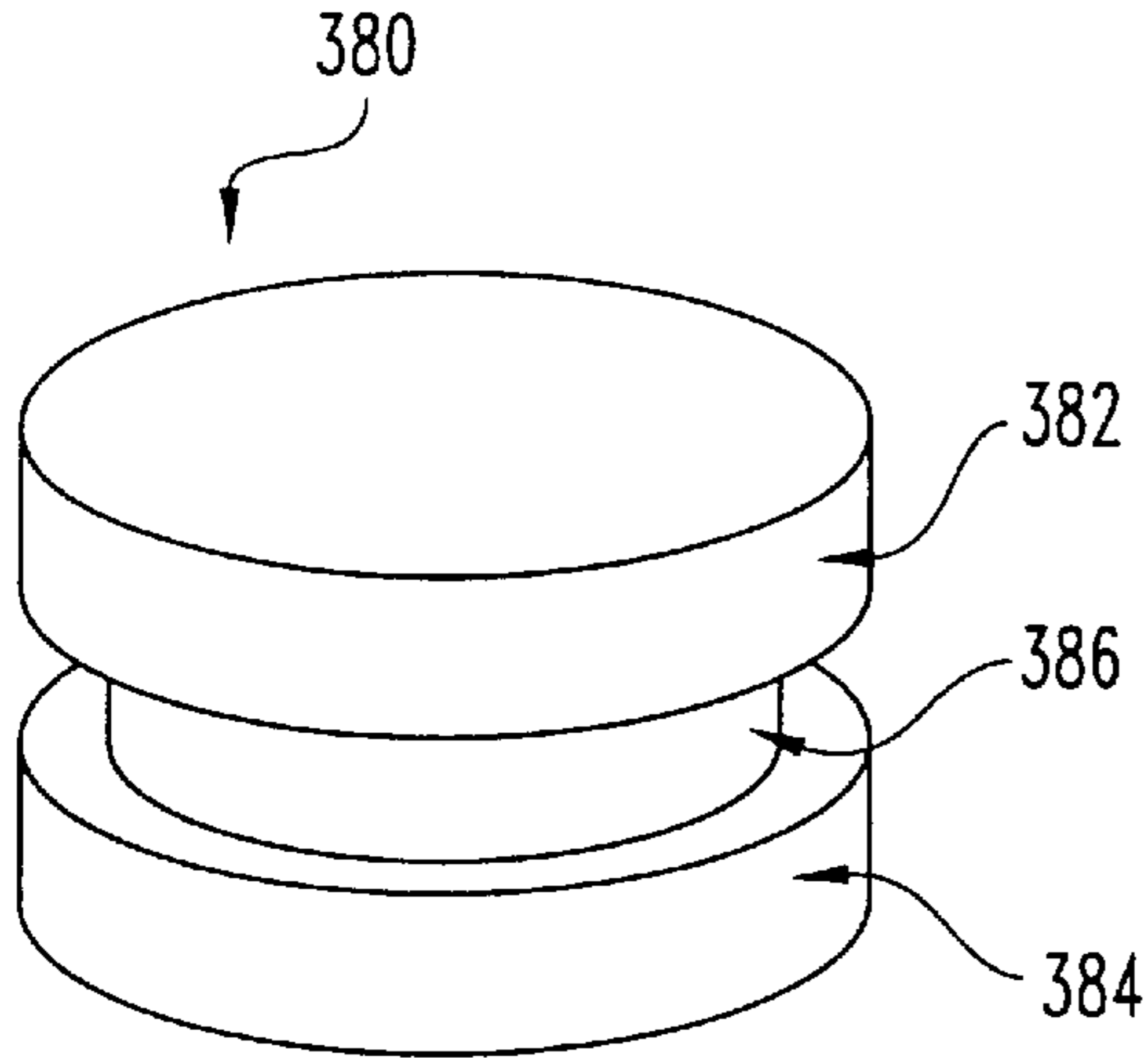


Fig. 40

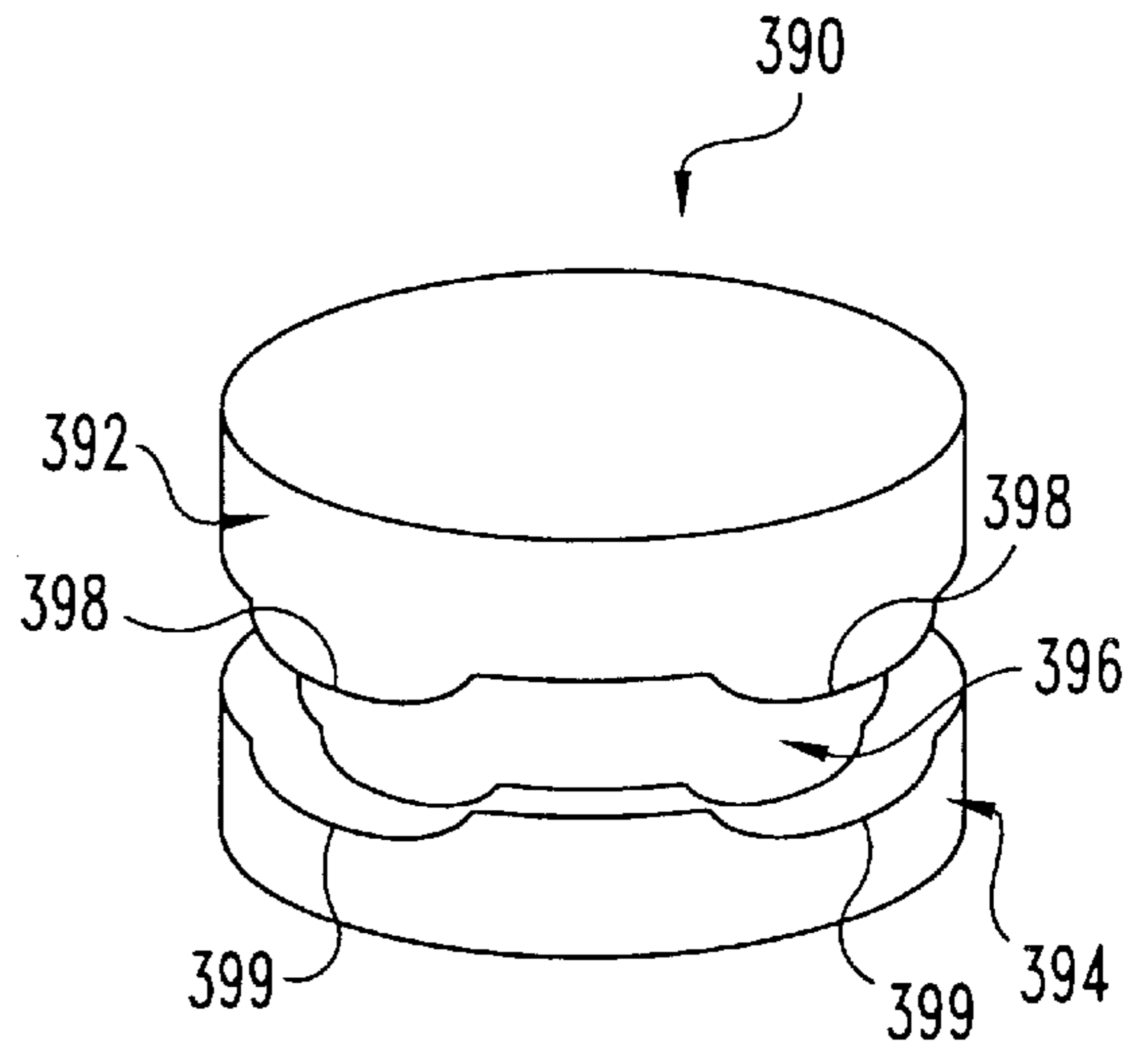


Fig. 41

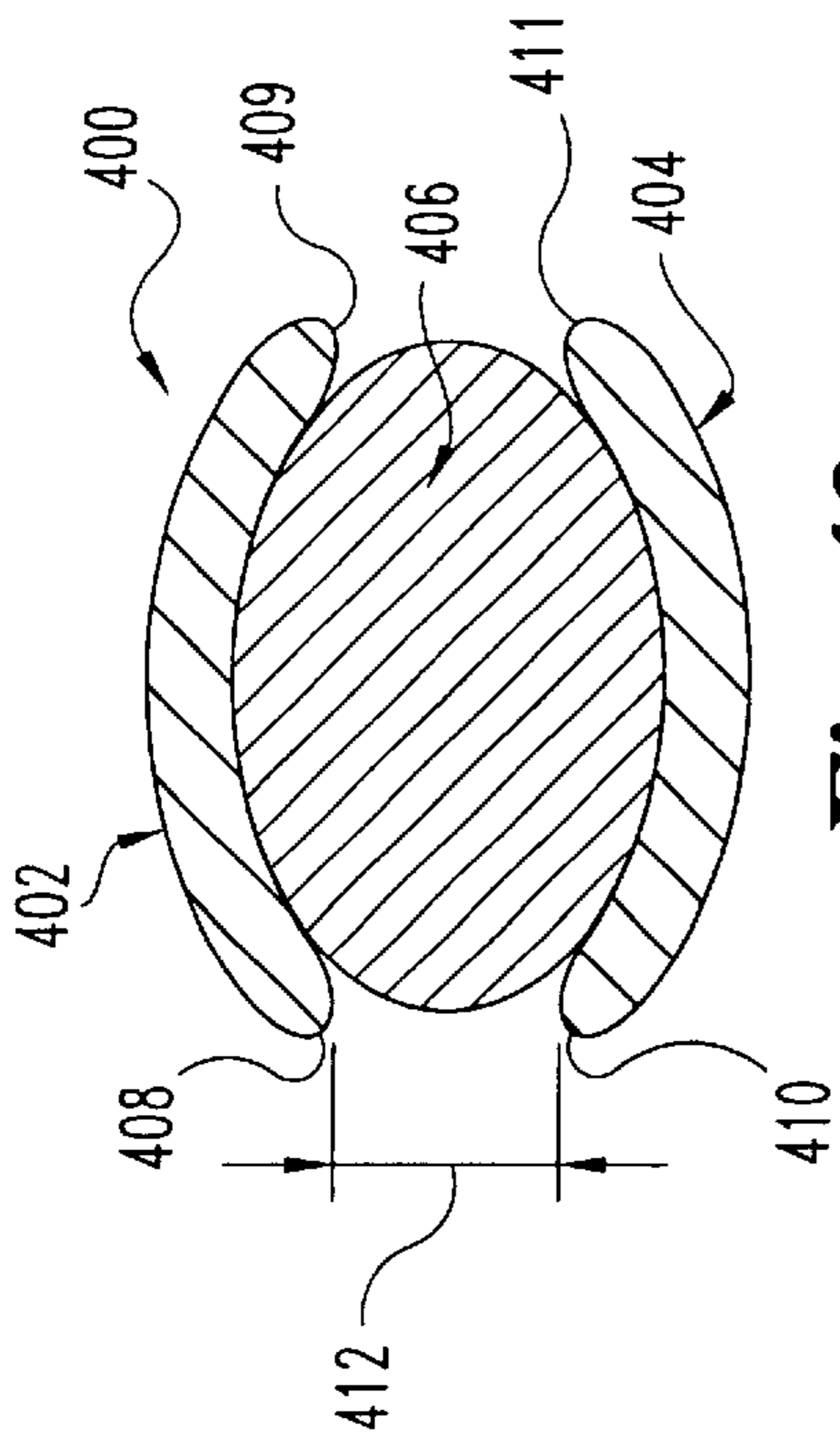


Fig. 42

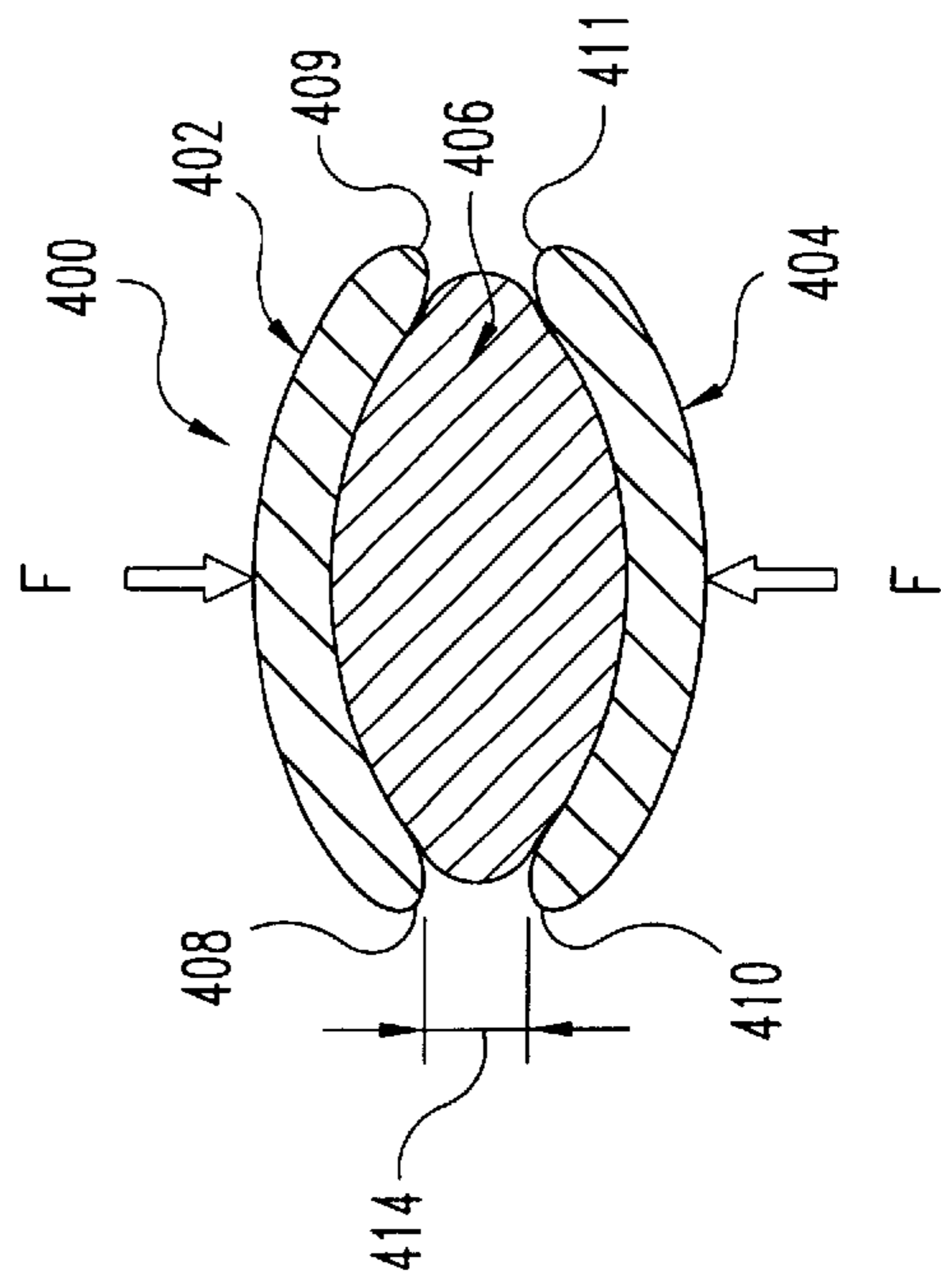


Fig. 43

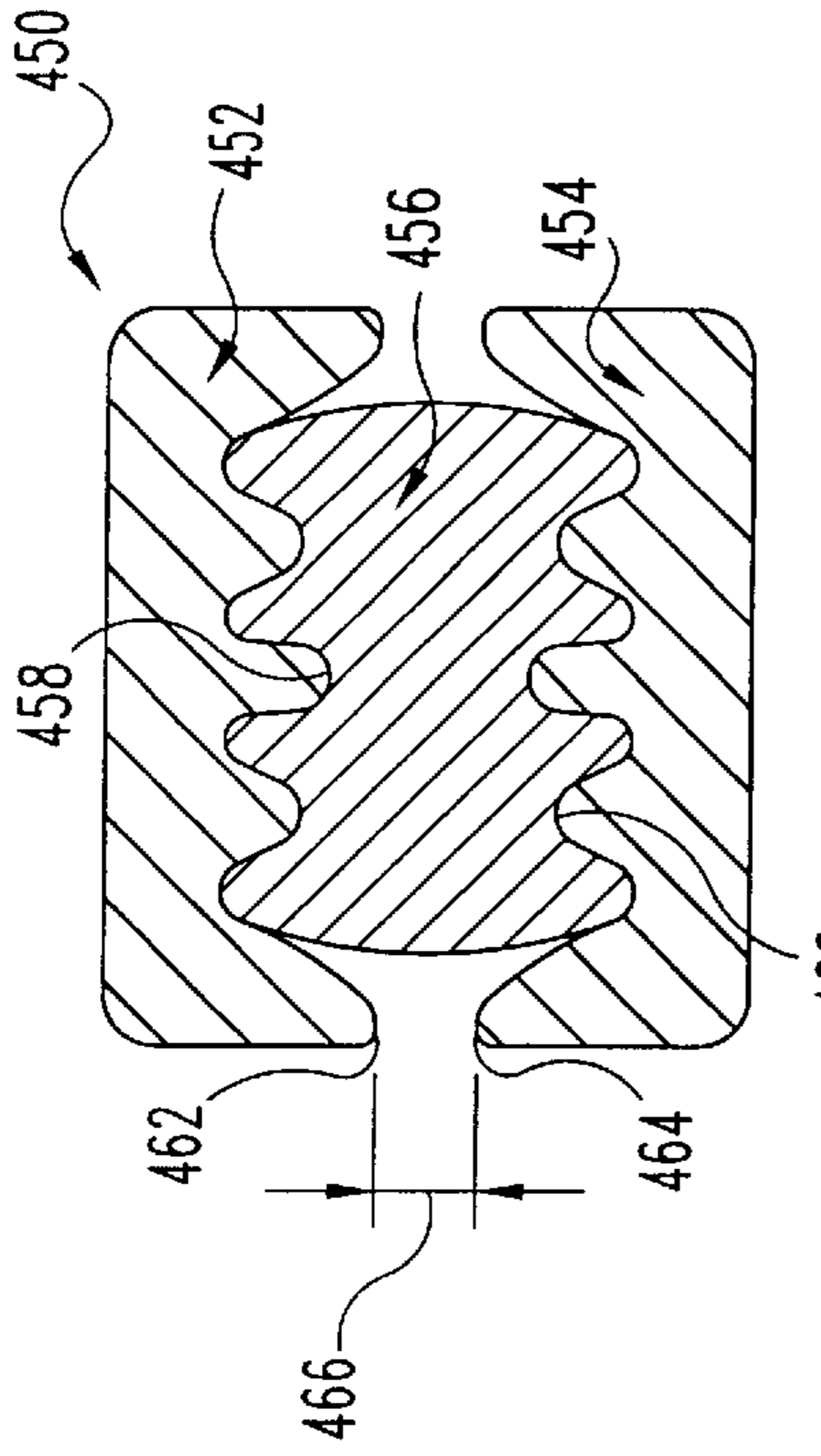


Fig. 44

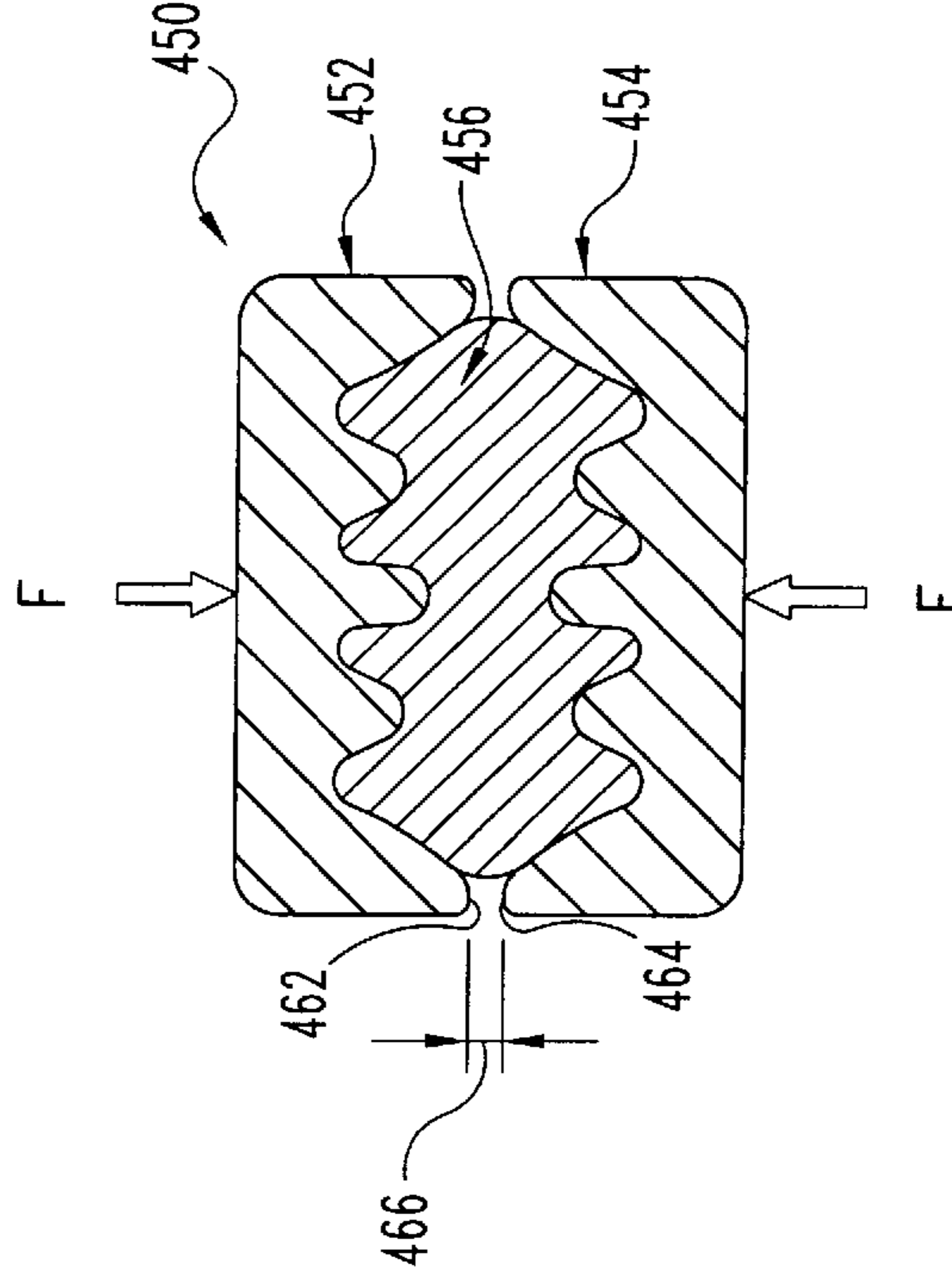


Fig. 45

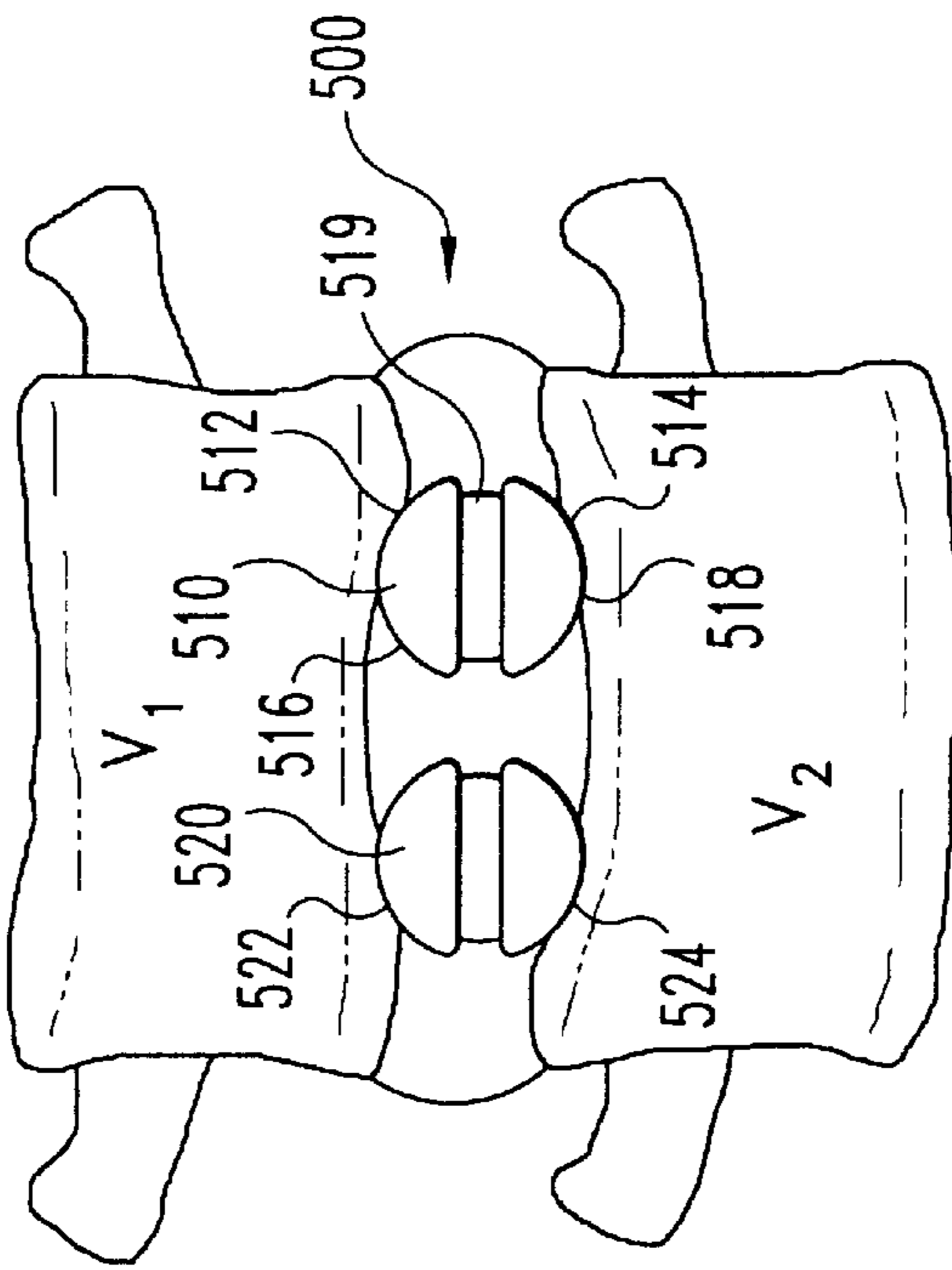


Fig. 46

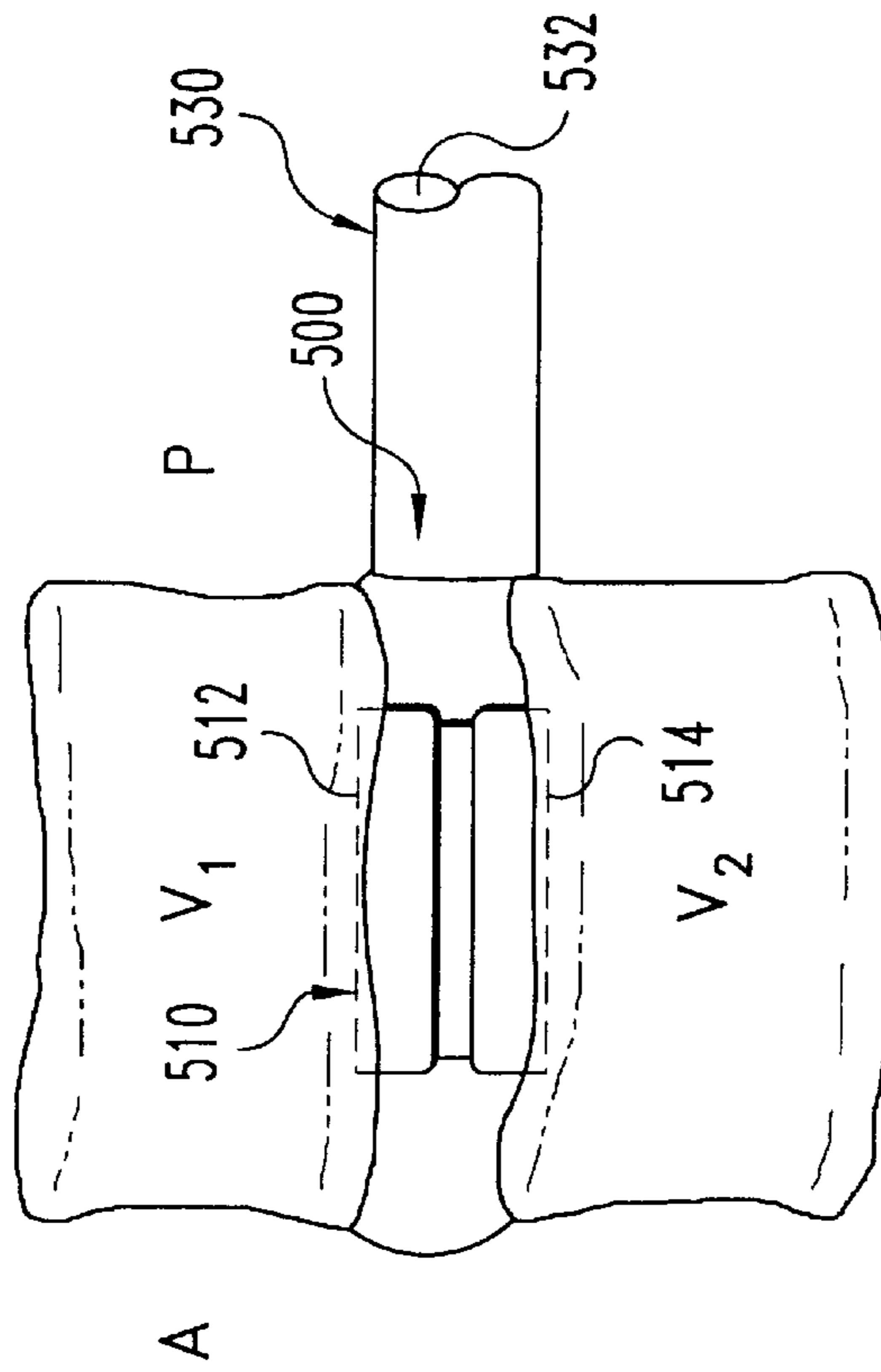
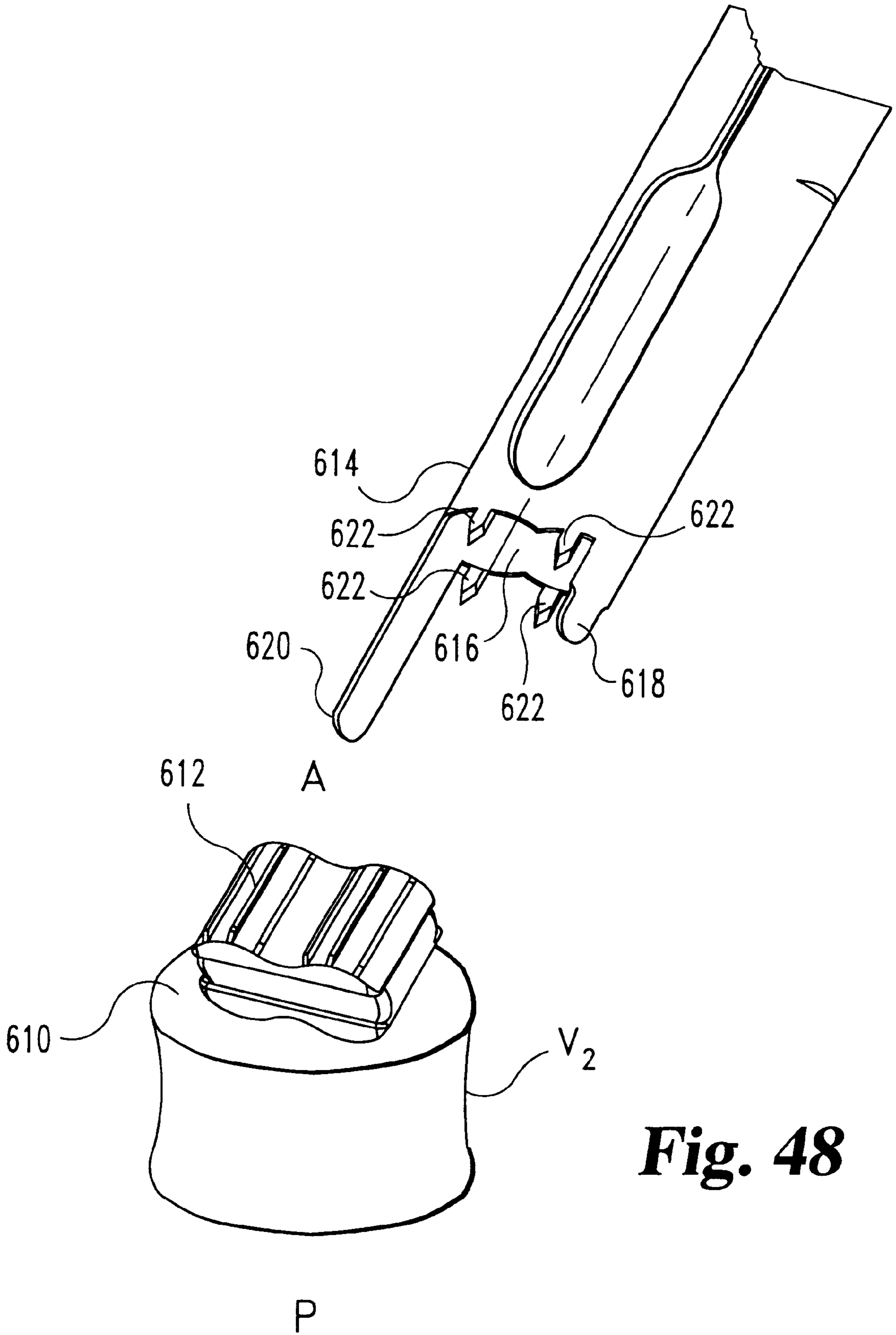


Fig. 47



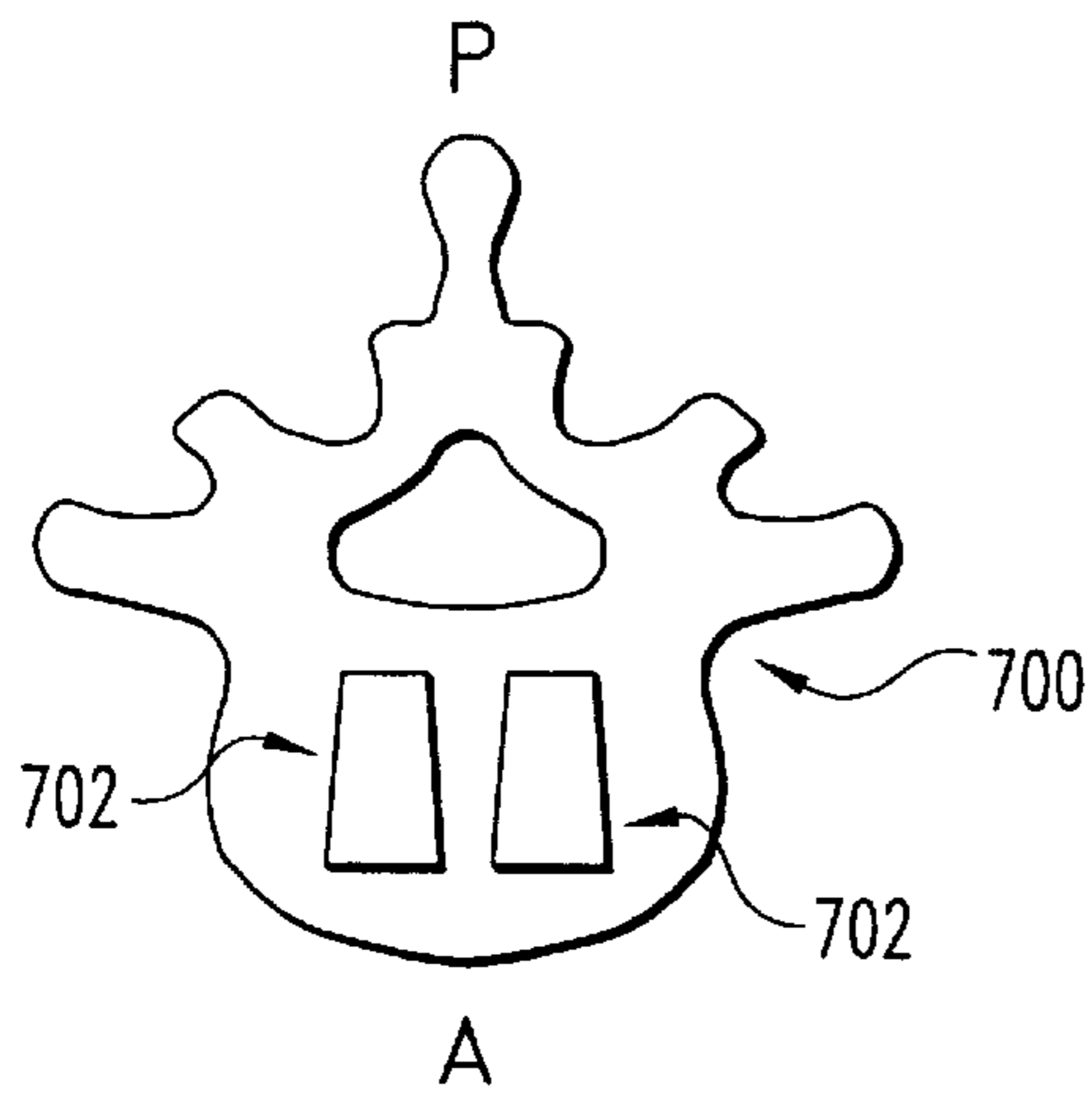


Fig. 49a

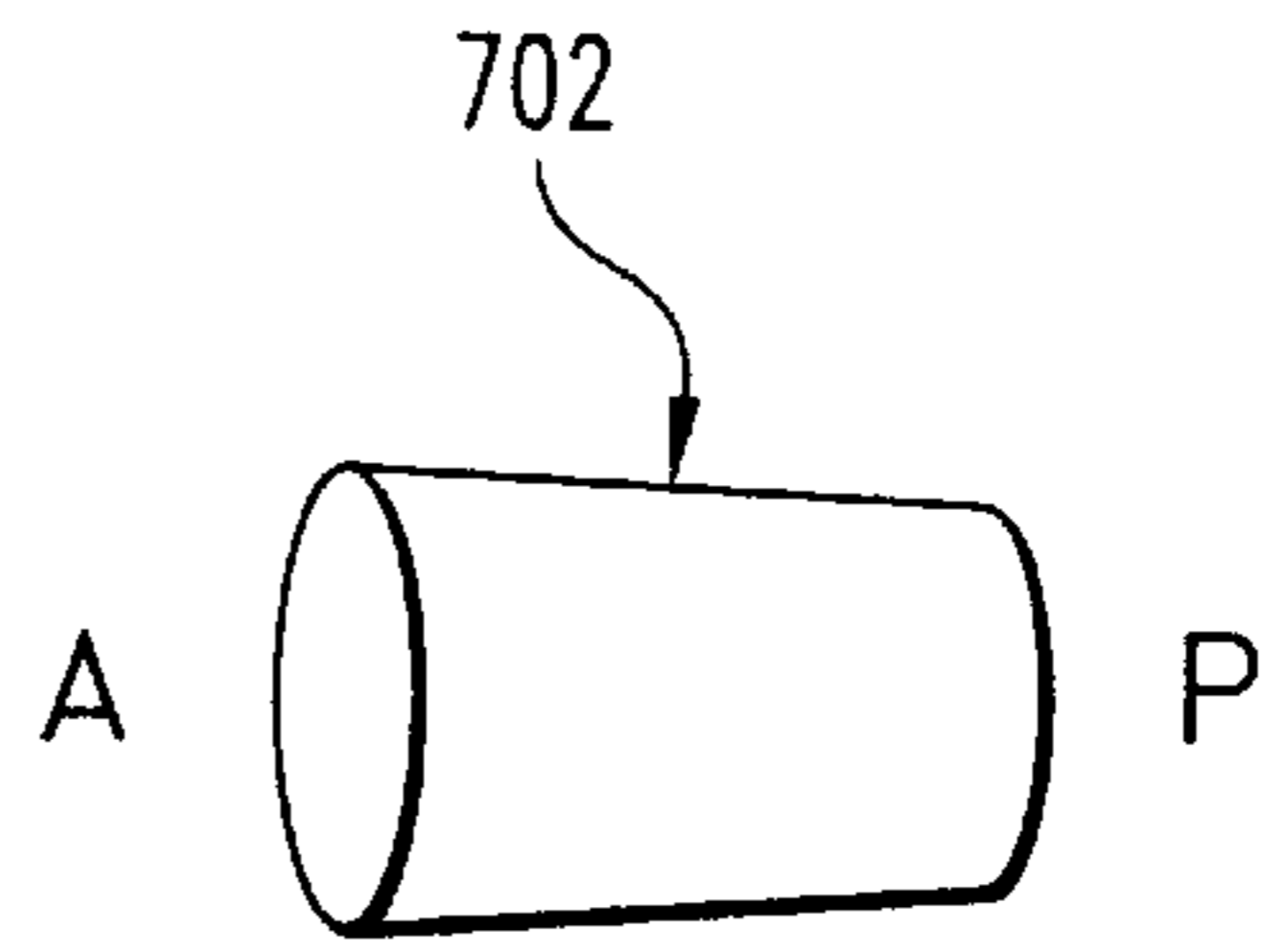


Fig. 49b

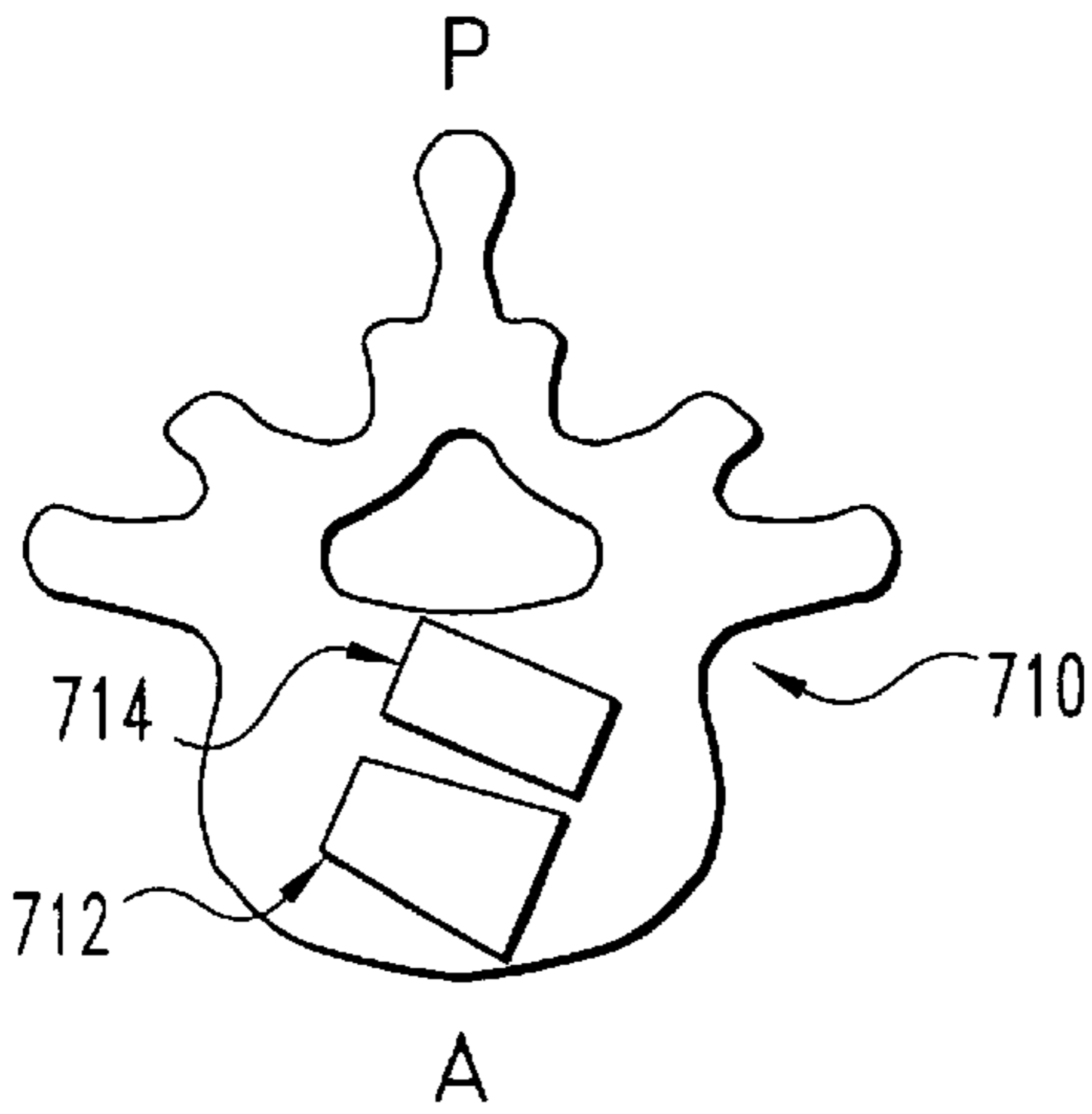


Fig. 50a

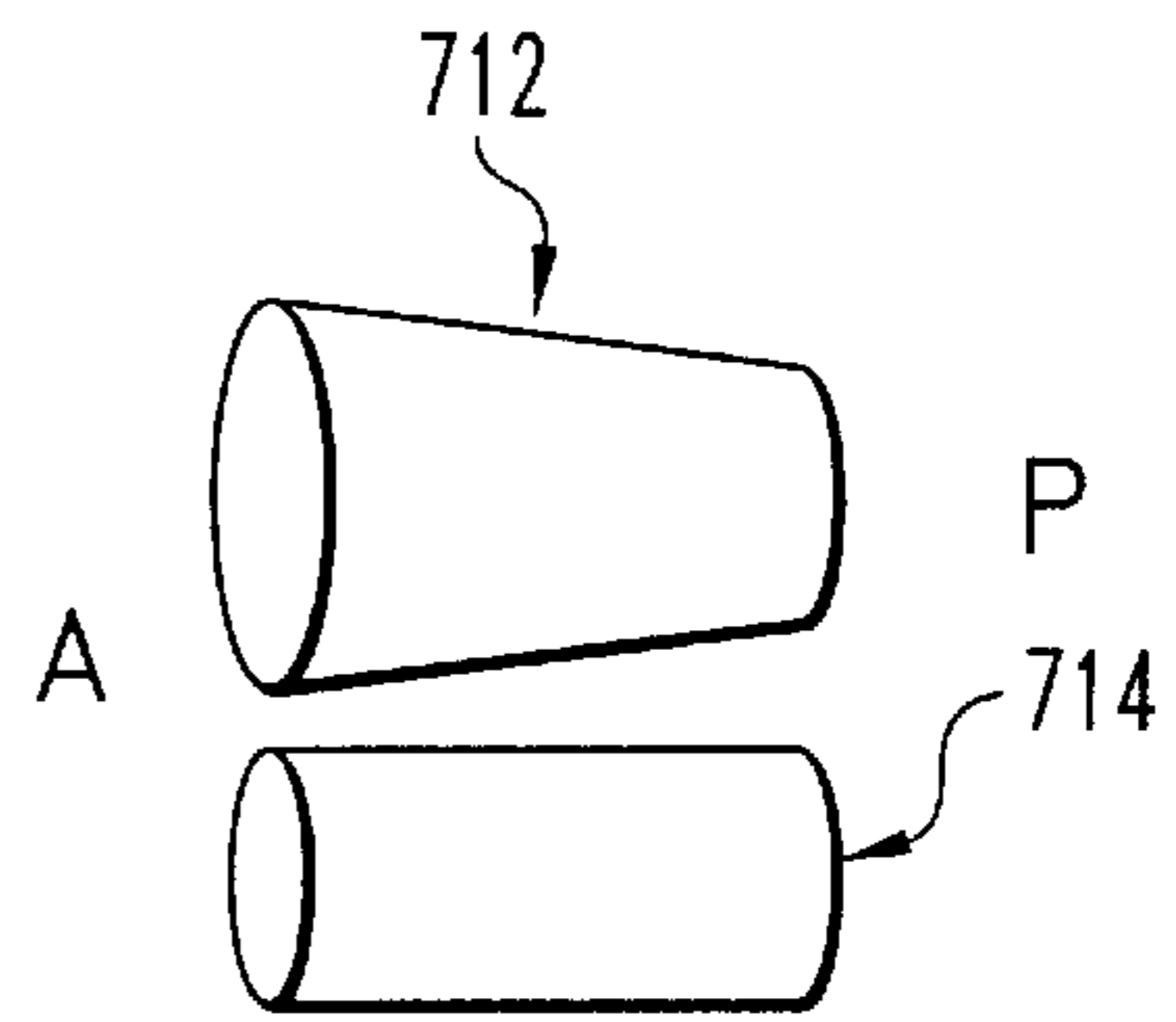


Fig. 50b

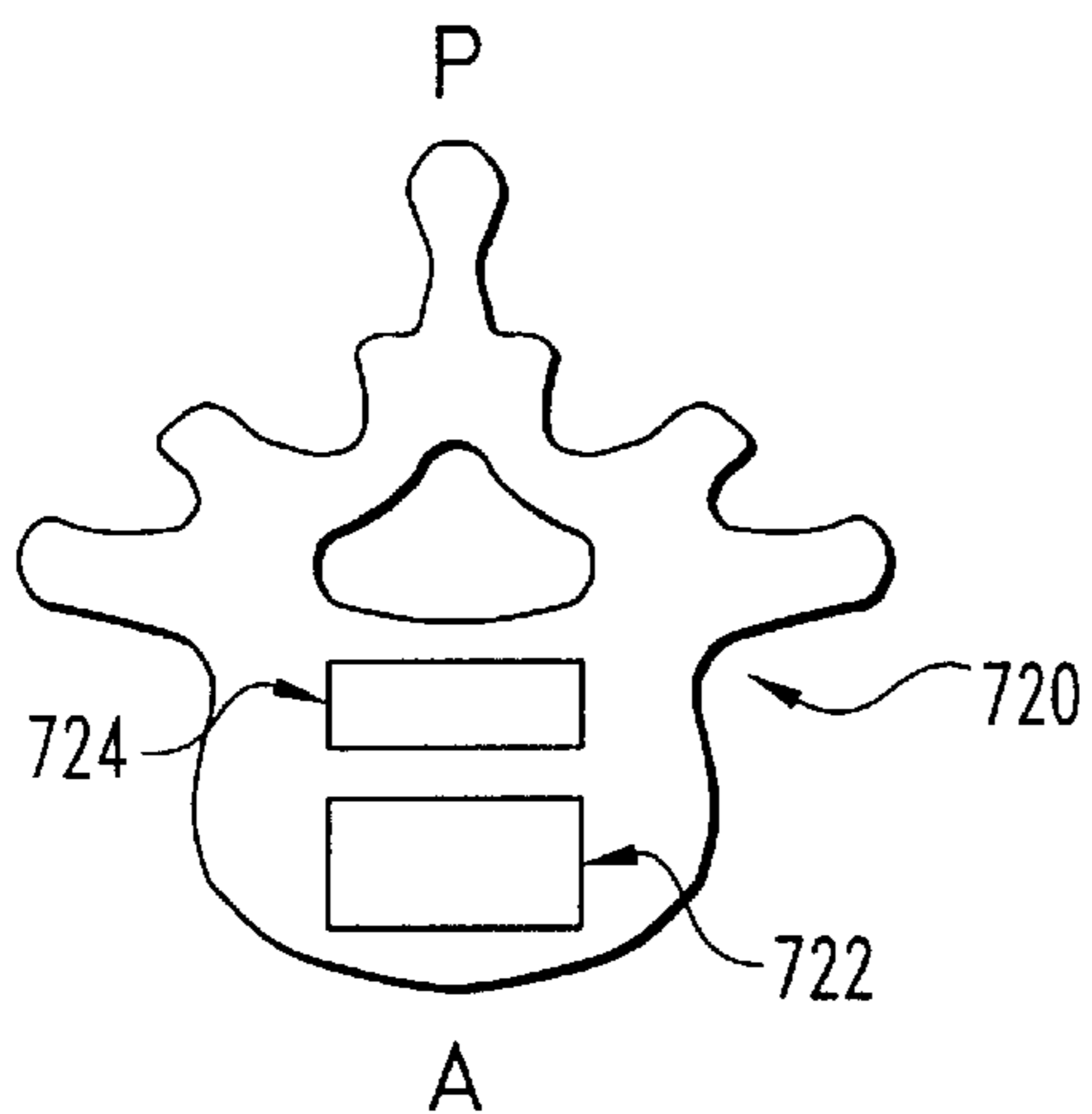


Fig. 51a

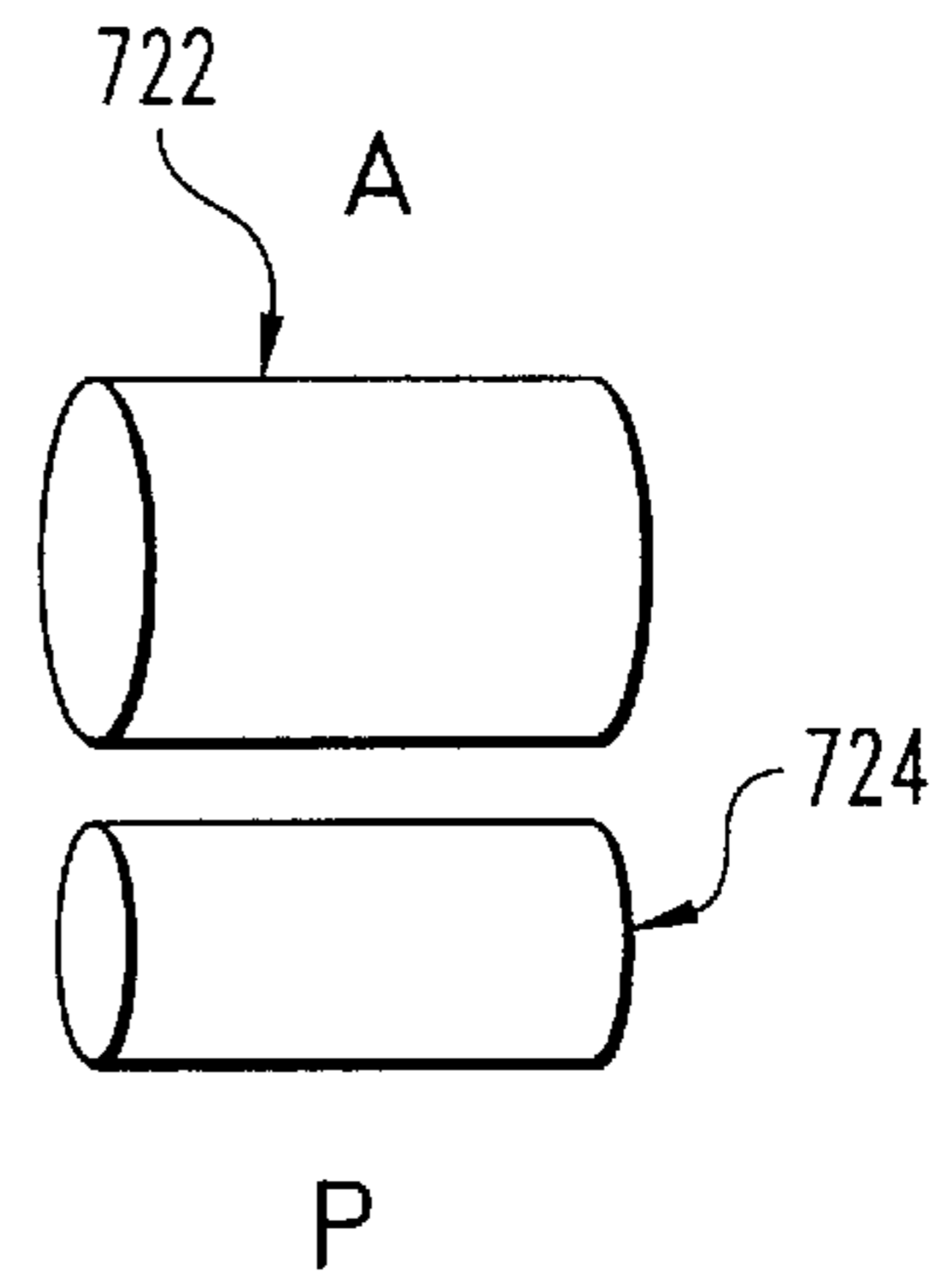


Fig. 51b

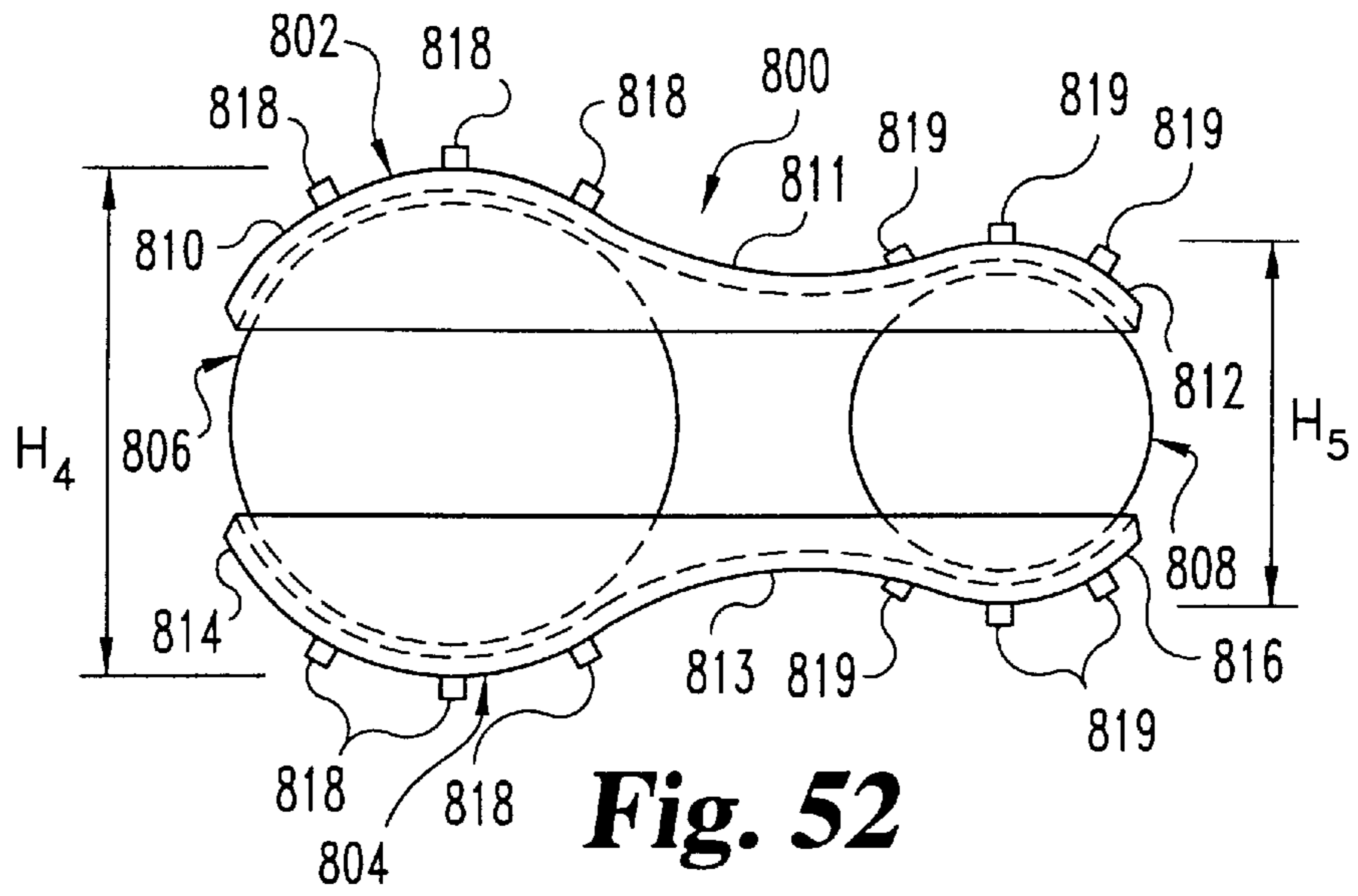


Fig. 52

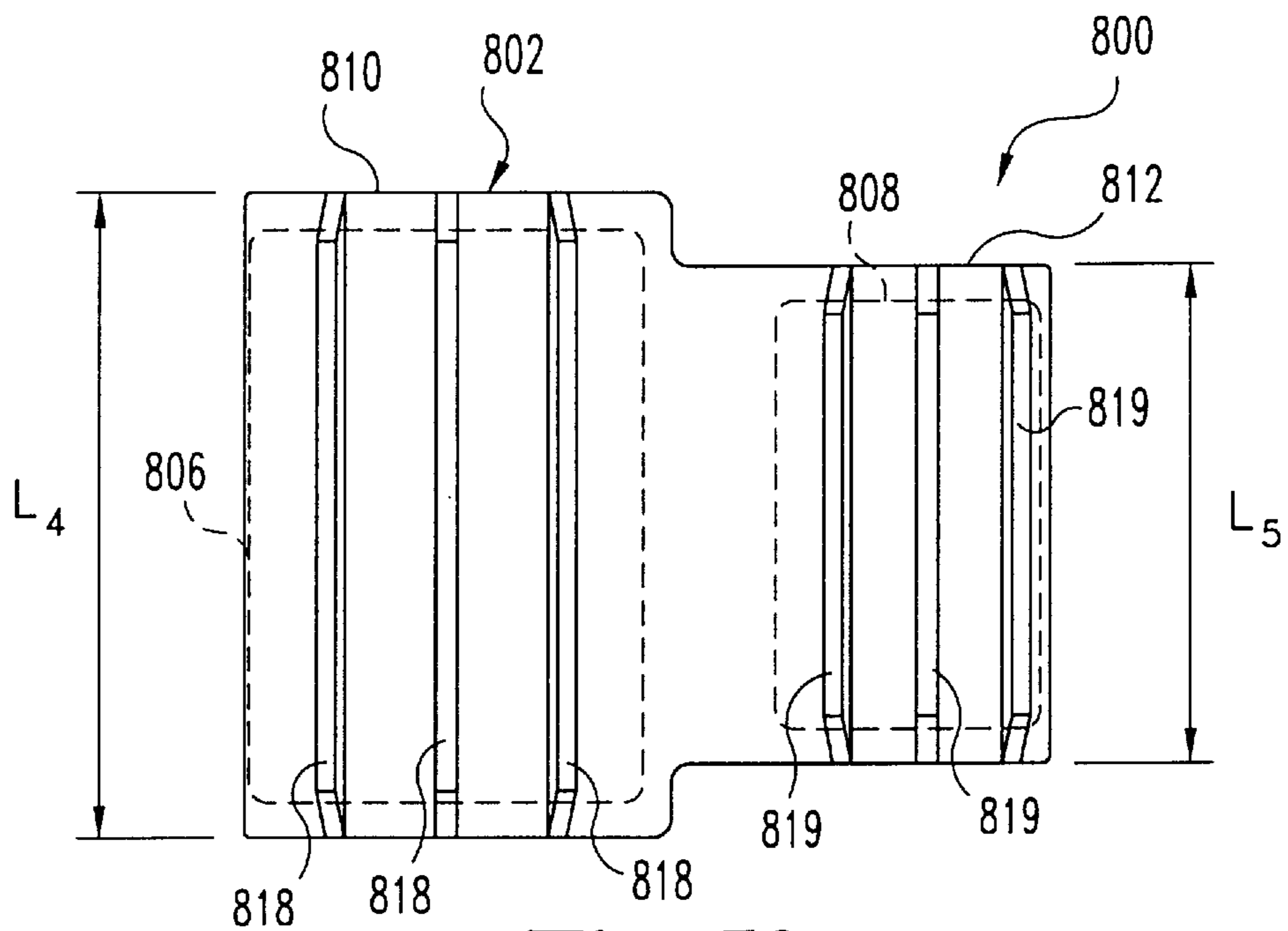


Fig. 53

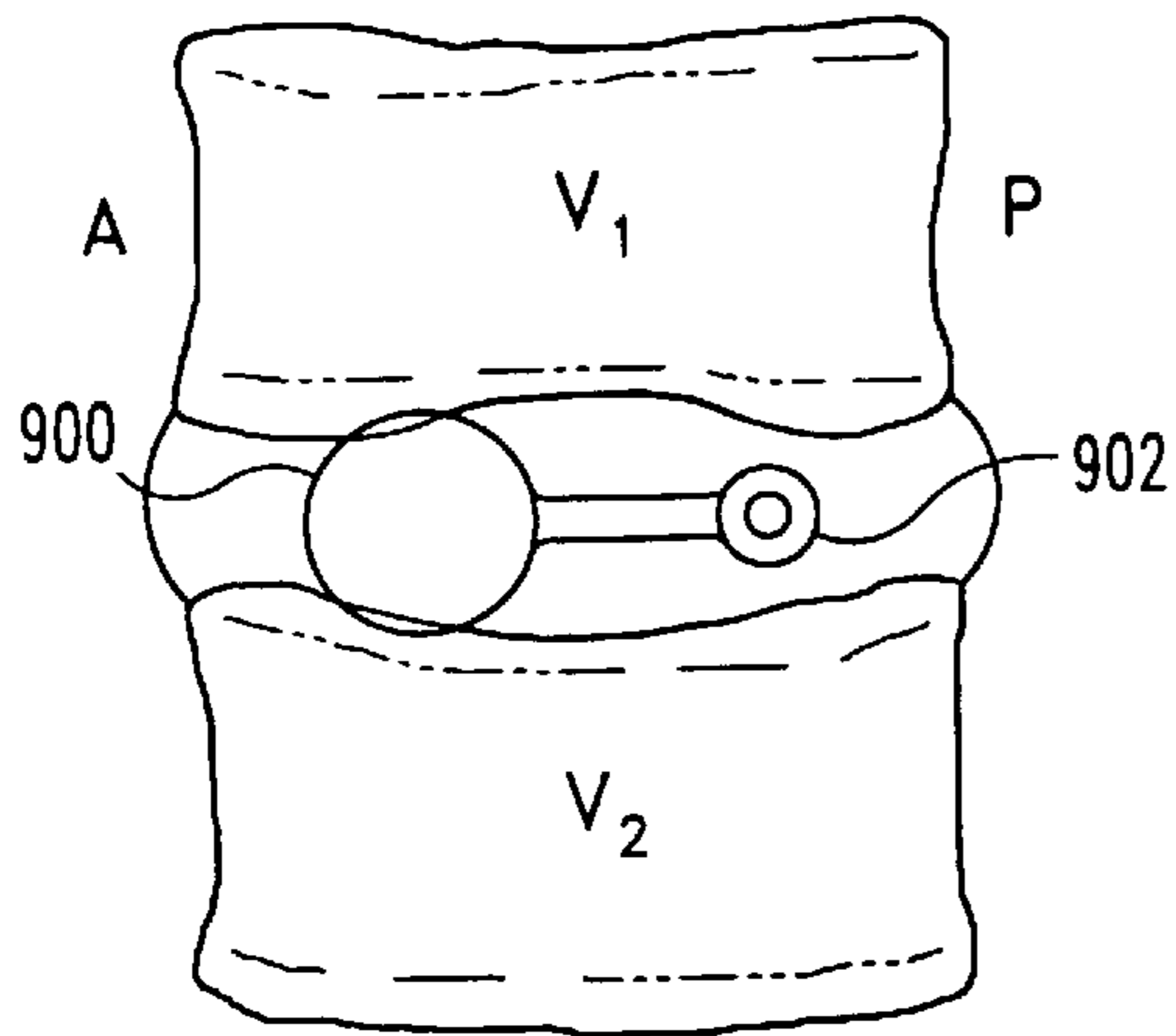


Fig. 54a

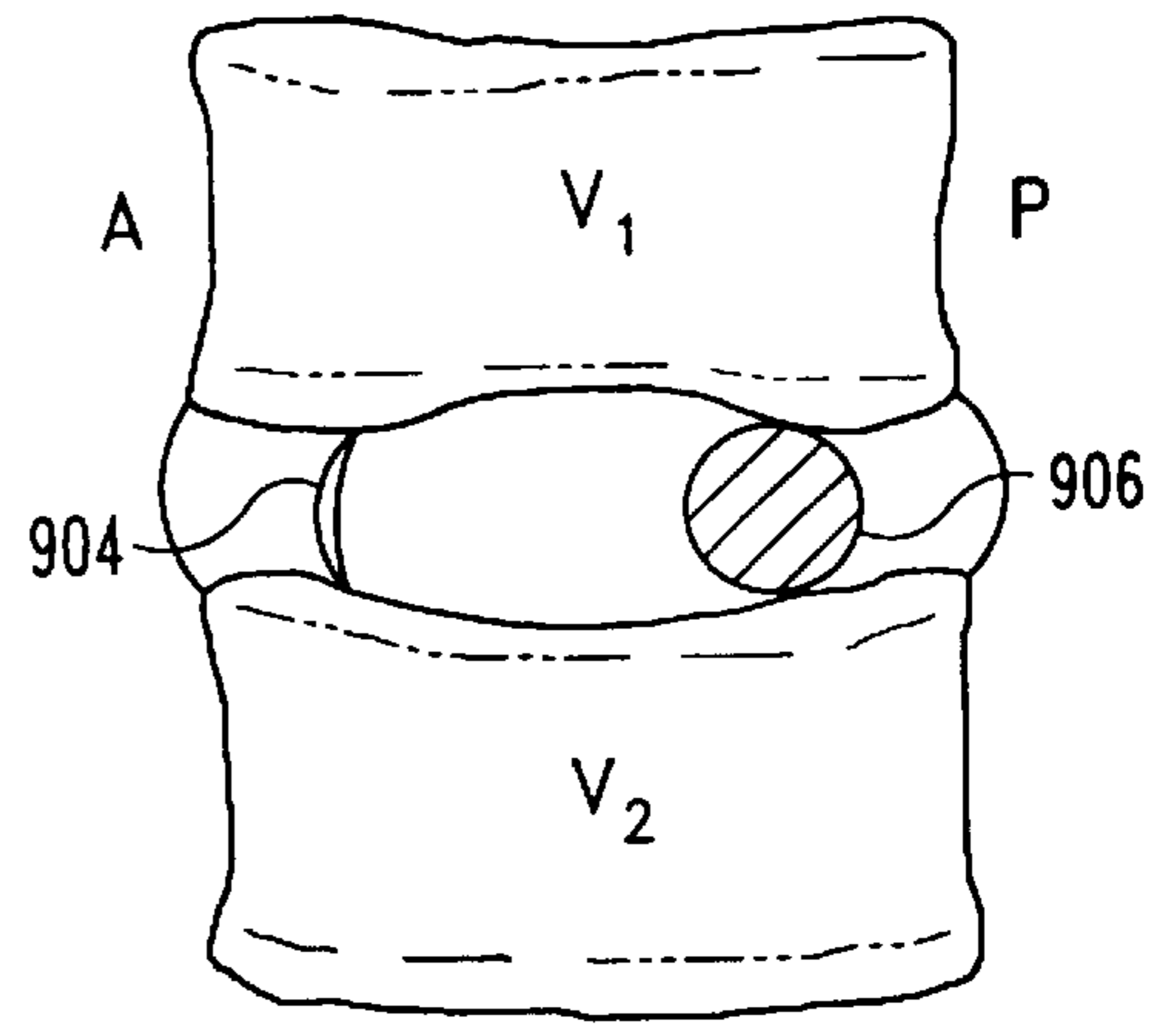


Fig. 54b

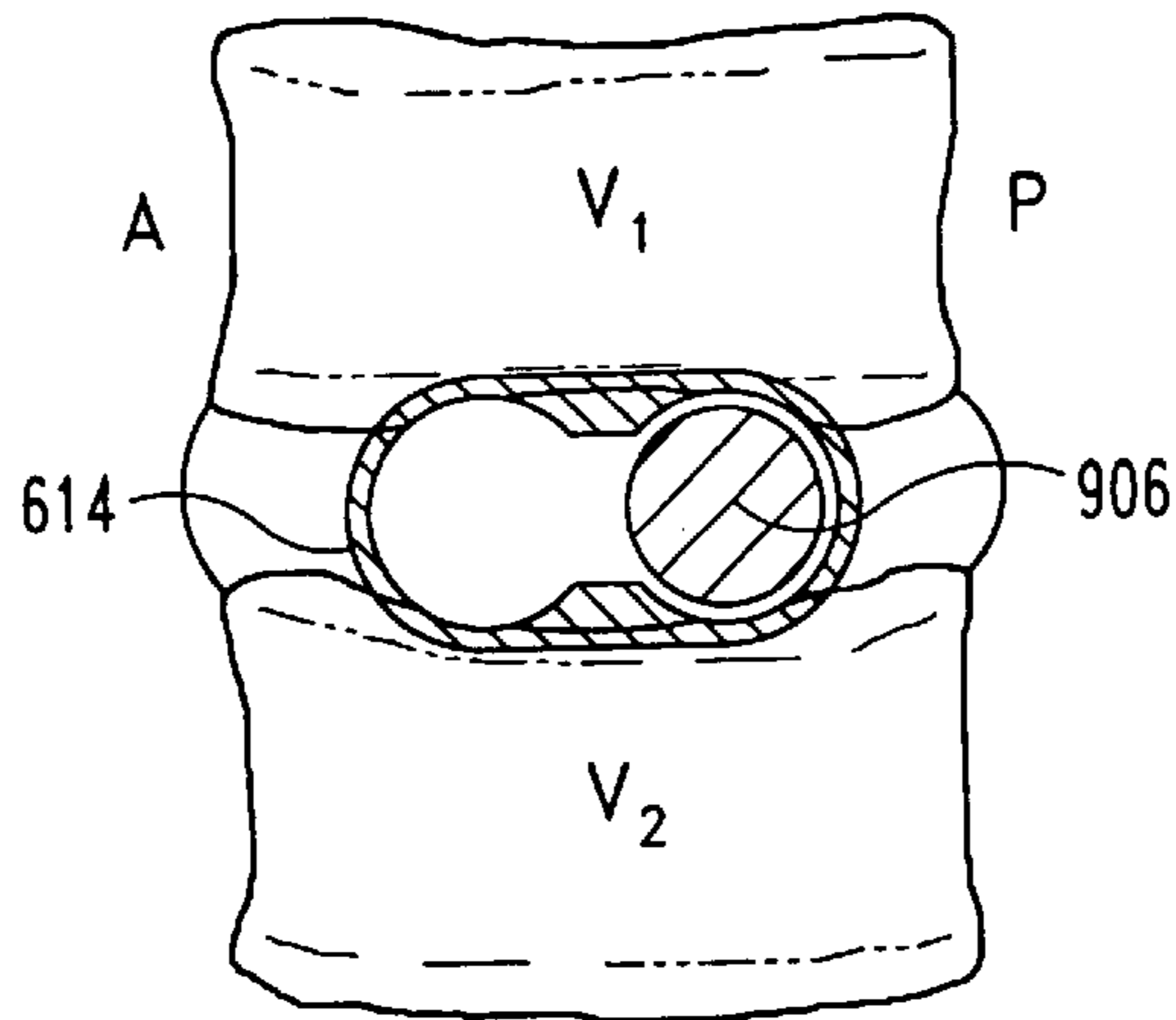


Fig. 54c

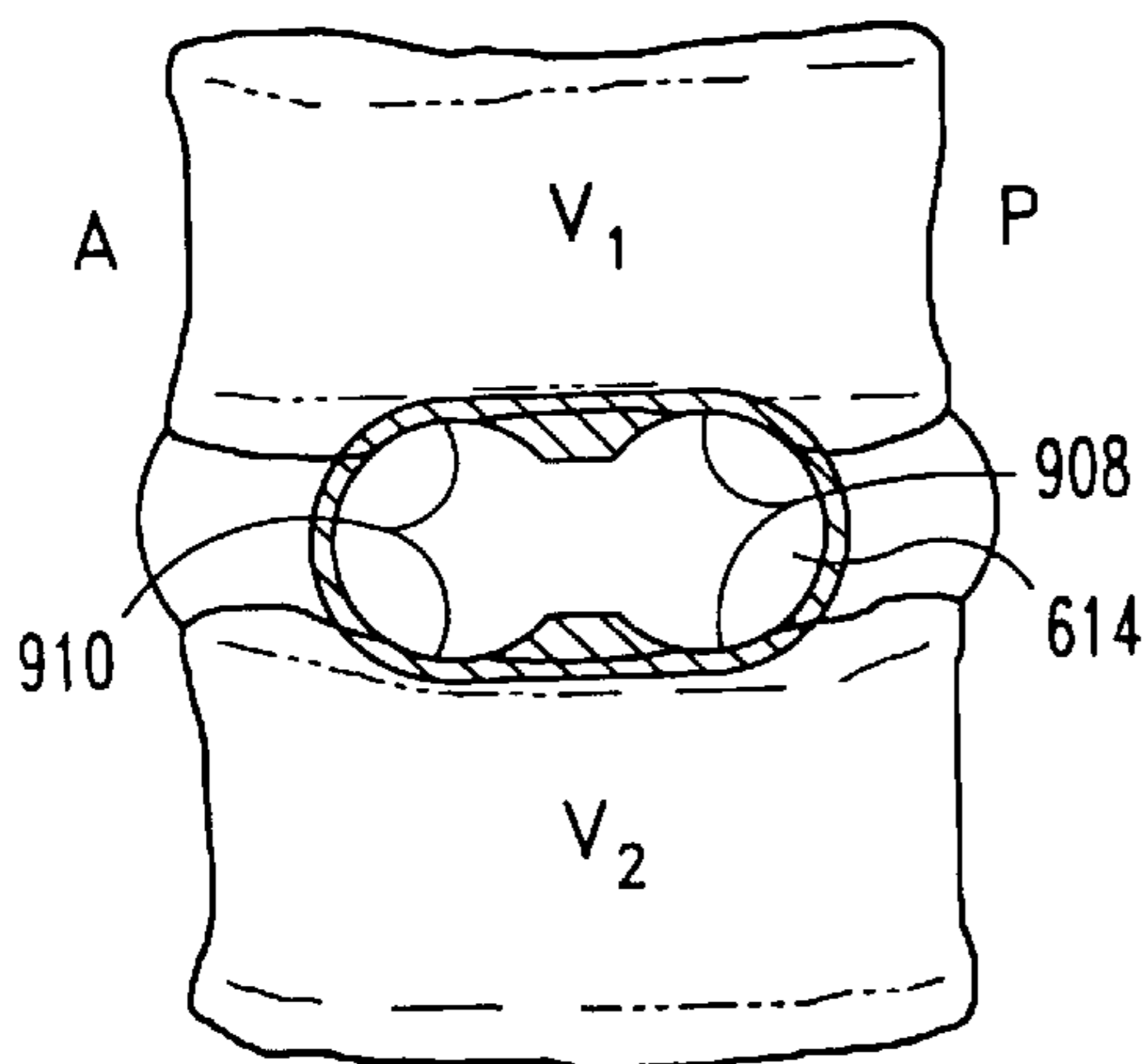


Fig. 54d

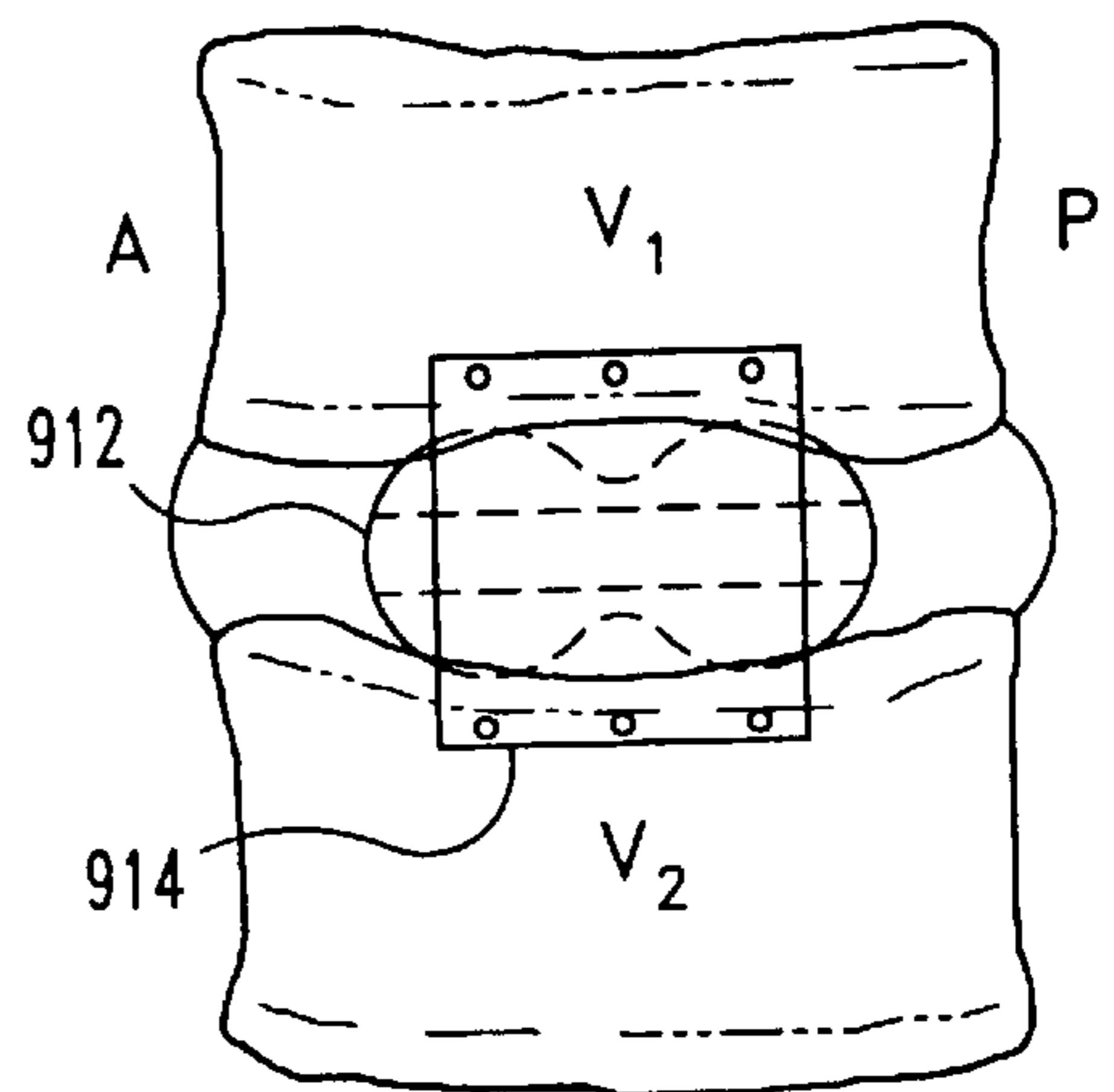


Fig. 54e

ARTIFICIAL DISC IMPLANT**CROSS-REFERENCE TO RELATED APPLICATIONS**

The present application claims the benefit of the filing date of Provisional Application Serial No. 60/137,586 filed Jun. 4, 1999, entitled **ARTIFICIAL DISC REPLACEMENT**. The referenced application is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

The present invention relates to artificial disc replacement devices. Previous attempts at artificial disc replacement have not received wide spread acceptance because of a number of problems. In some attempts at disc replacement, a flexible artificial disc is placed within the intervertebral disc space without any anchoring system, with the expectation that the artificial disc will remain in place in the disc space based on contact with the ligaments of the disc annulus and/or the vertebral bodies. With this approach there remains an unacceptable rate of protrusion of the artificial disc from the disc space. Further, over time the artificial disc may wear against the adjacent vertebral endplates, generating wear particles in the disc space and creating the risk of failure of the artificial disc.

Alternative designs have provided a rigid interface between the vertebral end plates and a shock absorbing compound disposed in the disc space between the rigid interfaces. The drawbacks of many of these prior devices are that they require extensive disc space preparation prior to placement. Other attempts at disc replacement provide a device having multiple components that must be positioned in the disc space.

The present invention is directed to providing improved artificial disc replacement implants directed to solving a number of the problems and disadvantages of the previous attempts at disc replacement.

SUMMARY OF THE INVENTION

The present invention provides an improved artificial disc implant for replacing the spinal disc between two vertebrae of the spine. The implant comprises an upper shell, a lower shell and a spacer or insert therebetween. Preferably the implant is insertable as a single unit into the disc space between two adjacent vertebral bodies. The shells may be made from any suitable bio-compatible material.

According to one aspect of the invention, the upper and lower shells each include a pair of interconnected cylindrical lobes. In one form, the upper and lower shells are partially cylindrical.

Further, the present invention contemplates insertion into the disc space via tubular instruments presently used for interbody fusion procedures. Thus, the instrumentation utilized to perform current interbody fusion techniques may also serve a dual function for disc replacement procedures.

In another aspect of the present invention, there is provided an upper and lower shell for engagement with the vertebral bone of the adjacent vertebral bodies. The upper and lower shells each have anchoring means to prevent movement in at least one direction. In one form, the anchoring means are ribs that prevent rotation of the shell in the disc space. In another form, each shell includes a flange extending therefrom. Each flange has an aperture extending therethrough receiving a bone screw to engage the shell to the adjacent vertebra.

Another aspect of the present invention, there is provided mating surfaces between the upper and lower shells to restrict the transmission of shear forces through the spacer disposed between the upper and lower shells. In one form, the mating surfaces are provided by multiple projections and that are positionable in corresponding recesses to restrict movement in multiple directions while permitting compression of the spacer disposed between the upper and lower shells.

In still a further aspect of the present invention, shells for contacting the upper and lower vertebral end plates are provided to anchor the device, and multiple spacer shapes are provided between the shells to permit insertion from a variety of approaches to the disc space, including anterior, posterior, lateral, anterior-lateral, and posterior-lateral approaches. The multiple spacer shapes are configured to address a variety of angulations between the adjacent vertebrae. Various instruments and methods for insertion one or more artificial disc implants to the disc space from a variety of approaches are also provided.

In yet another aspect of the present invention, the spacer includes two interconnected cylindrical portions and the upper and lower shells have cavities shaped to securely retain the spacer therebetween.

In a further aspect of the invention, the spacer is inserted between the upper and lower shells. The sidewalls of the spacer are truncated adjacent the gap between the upper and lower shells to limit potential impingement of the material between the upper and lower shells as the spacer is compressed.

In yet another aspect of the preferred invention, each of the upper and lower shells includes a substantially cylindrical bone engagement surface for contact with a substantially cylindrical bone opening in the vertebral end plates. Preferably, the shells include structure to engage the bone beyond the opening to limit movement of the shells in at least one direction.

According to another aspect of the present invention, the implant includes a spacer formed from a hydrogel substance. In one method of inserting the implant according to the present invention, the hydrogel is at least slightly dehydrated thereby reducing the height of the implant for insertion. Once inserted, the hydrogel can be hydrated to increase the overall height of the implant to the desired working height.

These and other aspects, features, embodiments, forms, and advantages of the invention will become apparent from the following description of the illustrated embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of an artificial disc implant according to the present invention.

FIG. 2 is a side view of the artificial disc implant of FIG. 1 rotated 90 degrees about its axis.

FIG. 3 is an end view of the implant of FIG. 1.

FIG. 4 is a partial cross-sectional view of the implant of FIG. 2 taken along line 4—4 with spacer removed.

FIG. 5 is a side view of a spacer for the implant of FIG. 1.

FIG. 6 is an end view of the spacer of FIG. 5.

FIG. 7 is a perspective view of another embodiment of an artificial disc implant according to the present invention.

FIG. 8 is an end view of the implant of FIG. 7.

FIG. 9 is a side view of the implant of FIG. 7.

FIG. 10 is an end view of a shell comprising a portion of the implant of FIG. 7.

FIG. 11 is a top view of the shell of FIG. 10.

FIGS. 12 and 12a are each cross-sectional views of the shell taken along line 12—12 of FIG. 11.

FIG. 13 is a cross-sectional view of the shell taken along line 13—13 of FIG. 11.

FIG. 14 is a side view of the shell of FIG. 10.

FIG. 15 is a perspective view of still another embodiment of an artificial disc implant according to the present invention.

FIG. 16 is an end view of the implant of FIG. 15.

FIG. 17 is a side view of the implant of FIG. 15.

FIG. 18 is an end view of a shell comprising a portion of the implant of FIG. 16.

FIG. 19 is a top view of the shell of FIG. 18.

FIG. 20 is a cross-sectional view of the shell taken along line 20—20 of FIG. 19.

FIG. 21 is a cross-sectional view taken of the shell along line 21—21 of FIG. 19.

FIG. 22 is a side view of the shell of FIG. 18.

FIG. 23 is a perspective view of a further embodiment of an artificial disc implant according to the present invention.

FIG. 24 is a perspective view of a spacer utilized in the implant of FIG. 23.

FIG. 25 is an end view of an alternate form of the implant of FIG. 23.

FIG. 26 is a top view of the implant of FIG. 23.

FIG. 27 is a cross-sectional view of the implant taken along line 27—27 of FIG. 25.

FIG. 28 is a perspective view of another embodiment of an artificial disc implant according to the present invention.

FIG. 29 is a side view of the implant of FIG. 28 with the external thread pattern not shown.

FIG. 30 is an end view of the implant of FIG. 29.

FIG. 31 is a cross-sectional view taken along line 31—31 of FIG. 30.

FIG. 32 is a cross-sectional view taken along line 32—32 of FIG. 29.

FIG. 33 is a perspective view of a further embodiment artificial disc implant according to the present invention.

FIG. 34 is a perspective view of yet a further embodiment of an artificial disc implant having a central extension to limit movement in at least one direction.

FIG. 35 is a perspective view of still a further embodiment artificial disc implant according to the present invention having a configuration to limit shear forces in the spacer.

FIG. 36(a) is a cross-sectional view similar to FIG. 32 showing an artificial disc implant having a spacer with truncated side walls adjacent the separation between the upper and lower shells.

FIG. 36(b) is a perspective view of the spacer shown in cross-section in FIG. 36(a).

FIG. 37 shows the implant of FIG. 36(a) in a compressed state with the truncated side walls compressed to make contact between the upper and lower shells.

FIG. 38 is another embodiment of an artificial disc implant according to the present invention having a rectangular or square upper and lower shells.

FIG. 39 is the implant of FIG. 38 having upper and lower shells configured to limit shear forces in the spacer.

FIG. 40 is another embodiment of an artificial disc implant according to the present invention having substantially circular upper and lower shells.

FIG. 41 is the implant of FIG. 40 having upper and lower shells configured to limit shear forces in the spacer.

FIG. 42 is a cross-sectional view of the relaxed state of a substantially cylindrical artificial disc implant according to the present invention having a spacer disposed between upper and lower partial cylindrical shells.

FIG. 43 shows the implant of FIG. 42 in a compressed state with the upper and lower shells positioned closer to each other.

FIG. 44 is a cross-sectional view of a relaxed state of an artificial disc replacement implant according to the present invention having upper and lower shells with substantially planar bone contacting surfaces and a spacer disposed therebetween.

FIG. 45 shows the implant of FIG. 44 in a compressed state.

FIG. 46 is an end view showing two of the implants of the present invention inserted into the disc space between two adjacent vertebral bodies.

FIG. 47 is a side view of the implants and disc space of FIG. 46.

FIG. 48 shows a partial perspective view of a disc space with an implant according to the present invention and being inserted by a substantially lateral approach to a disc space.

FIGS. 49(a) and 49(b) illustrate an implant having spacers shaped according to the present invention for insertion into the disc space from an anterior approach.

FIGS. 50(a) and 50(b) illustrate an implant having spacers shaped according to the present invention for insertion into the disc space from an antero-lateral approach.

FIGS. 51(a) and 51(b) illustrate an implant having spacers shaped according to the present invention for insertion into the disc space from a substantially lateral approach.

FIG. 52 is an end view of another embodiment artificial disc implant according to the present invention.

FIG. 53 is a top view of the artificial disc implant of FIG. 52.

FIGS. 54a–54e illustrate various steps of a surgical technique according to the present invention.

DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any such alterations and further modifications in the illustrated devices, and any such further applications of the principles of the invention as illustrated therein are contemplated as would normally occur to one skilled in the art to which the invention relates.

The present invention is directed to improved artificial disc implants used to replace the spinal disc in an animal subject. In one embodiment, the invention contemplates an insert or spacer made from elastomer or hydrogel having properties of elasticity similar to or equivalent to a natural spinal disc. The spacer or insert is disposed between, but preferably not interconnected with, an upper shell and a lower shell, each of which contact and/or engage an adjacent vertebral body.

Referring now to FIGS. 1–6, there is shown a first preferred embodiment of an artificial disc implant according to one aspect of the invention. More specifically, implant 10

includes an upper shell **12**, a lower shell **14**, and an intermediate insert or spacer **16**. Spacer **16** preferably has elastic properties substantially equivalent to the natural elastic properties of the human body's intervertebral disc. In the illustrated embodiment, upper shell **12** and lower shell **14** are substantially identical; however, it is contemplated that there could be differences between the upper and lower shells without deviating from the spirit and scope of the present invention. The shells may be formed of any suitable bio-compatible material. For example, but without limitation, the shells may be composed of stainless steel, titanium, polymers, carbon fiber, shape memory alloys, or porous material. In the description that follows, the description of upper shell **12** applies with like effect to lower shell **14**.

In the illustrated embodiment, upper shell **12** is partially cylindrical and includes a bone contacting surface **36** and lower shell **14** is partially cylindrical and includes a bone contacting surface **38**, each of which is substantially arcuate and extends about longitudinal axis **11** to form a substantially cylindrical surface. Bone contacting surface **36** is interrupted by a number of ribs **18a**, **18b** and **18c**, collectively referred to as ribs **18**, and bone contacting surface **38** is interrupted by a number of ribs **19a**, **19b** and **19c**, collectively referred to as ribs **19**. In the illustrated embodiment, three such retention ribs **18** and **19** are provided on each shell; however, a fewer number or greater number of ribs are also contemplated. While a straight uninterrupted rib **18**, **19** is shown in the preferred embodiment, it is contemplated that other retention mechanisms such as barbs, interruptions, scales, etc., may be utilized to assist in retention and engagement of the upper and lower shells with its adjacent vertebral bodies. Ribs **18** and **19** further resist rotation of implant **10** about its longitudinal axis **11** in the disc space.

As shown in FIG. **5** spacer **16** has a length **L1** along longitudinal axis **11**, and as shown in FIG. **6** has a cylindrical shape extending along longitudinal axis **11** with a diameter **D1**. Referring now to FIG. **2** upper shell **12** lower shell **14** each have a length **L2** that is greater than spacer **16** length **L1**. Upper shell **12** and lower shell **14** thus extend substantially beyond the spacer **16** length to form overhanging end portions **28** and **30** and overhanging end portions **35** and **37**, respectively, as shown in FIGS. **1** and **4**. Overhanging end portion **30** of upper shell **12** includes an end wall **32**, and a similar end wall **31** is included with overhanging end portion **28**. Overhanging end portion **37** of lower shell **14** includes an end wall **34**, and a similar end wall **33** is included with overhanging portion **35**. Upper shell **12** includes a tapered portion **26** extending from end wall **32** and through ribs **18** and a corresponding tapered portion **24** on the opposite end. Lower shell **14** includes a tapered portion **27** extending from end wall **34** and through ribs **19** and a corresponding tapered portion **25** on the opposite end. The tapered portions may assist in easing insertion of the device through an insertion apparatus, such as a sleeve, and into the disc space.

Referring to FIG. **4**, upper shell **12** includes the combination of partially cylindrical interior bearing wall **48** and end walls **31** and **32** to create an interior cavity or chamber **44** adapted to receive at least a portion of spacer **16** therein. Lower shell **14** similarly includes the combination of preferably cylindrical interior bearing wall **49** and end walls **33** and **34** to create an interior cavity or chamber **46** adapted to receive at least a portion of spacer **16** therein. The combination of interior chambers **44** and **46** cooperate to receive the cylindrically shaped spacer **16** and restrain movement of spacer **16** in shells **12**, **14**. In the illustrated embodiment, the

junctions between interior bearing wall **48** and end walls **31**, **32** are curved to form an arcuate surfaces **42**, **43** respectively, to limit abrupt changes in the surface configuration that might be encountered by the spacer **16**. Lower shell **14** similarly includes arcuate surfaces **47**, **45** formed at the junction of bearing wall **49** and end walls **33**, **34**, respectively.

As shown in FIG. **3**, implant **10** has an overall height in the disc space measured from upper bone contacting surface **36** to lower bone contacting surface **38**. Preferably, upper shell **12** has a height **H1** between bone contacting surface **36** and its lower edge, lower shell **14** has a height **H3** between bone contacting surface **38** and its upper edge, and spacer **16** comprises the remaining portion of the device height with a height **H2** extending between the edges of upper shell **12** and lower shell **14**. It will be understood that as load is applied to the upper and lower shells, **H1** and **H3** will remain substantially constant while **H2** will vary based on the applied load and the properties of spacer **16**. Furthermore, in a preferred embodiment **H2** is substantially greater than either **H1** or **H3**, and **H1** and **H3** are the same. In a further embodiment, greater than fifty percent of the spacer height is unconstrained by the upper or lower shells permitting substantial movement in the spacer to absorb compressive loads applied to implant **10** while preserving disc motion.

The three components of top shell **12**, spacer **16**, and lower shell **14** are preferably inserted into an intervertebral disc space as a single unit. The upper and lower shells may be urged towards one another to compress spacer **16**. In a compressed condition, the entire implant may be loaded into a delivery tube or sleeve which will maintain at least a portion of the compression during insertion. The entire implant may then be positioned adjacent the disc space and forcibly urged into the disc space by pushing on the trailing portion of each of the shells to urge the leading portion of implant **10** forwardly into the disc space. Preferably, a portion of the disc space has been prepared to create a substantially cylindrical area on the adjacent vertebrae adapted to receive the partially cylindrical portions of upper shell **12** and lower shell **14**. Ribs **18**, **19** extend beyond the prepared portion of the disc space and embed in adjacent bone, and the bone contacting surfaces **36**, **38** are intended to substantially abut the prepared disc space area to inhibit subsidence. More preferably, the prepared portion of the disc space may be limited to the area necessary to receive the length of implant **10** while leaving unprepared portions anterior and posterior of the inserted implant **10**. The unprepared anterior and posterior portions of bone may engage the end walls of the upper and lower shells to resist expulsion of implant **10** from the disc space.

In yet a further aspect of the invention, it is contemplated that spacer **16** may be comprised of hydrogels of various forms. It is contemplated that an alternative to or in conjunction with forcibly compressing the entire implant **10**, the interior of spacer **16** can be accessed via a syringe, access port, or the like to at least partially dehydrate the hydrogel, thereby assisting in reduction of the height of implant **10** between the upper and lower bone contacting surfaces **36**, **38**. The reduction in implant height facilitates insertion of implant **10** into the disc space through a smaller opening than could be utilized with an expanded implant **10**. Once positioned in the disc space, the hydrogel may be rehydrated to thereby fully expand spacer **16** and restore implant **10** to the desired height in the disc space.

Referring now to FIG. **7**, there is shown a further preferred embodiment of an artificial disc implant according to another aspect of the invention. Implant **50** includes an

upper shell **52**, a lower shell **54**, and a spacer **56** disposed therebetween. Implant **50** includes a longitudinal axis **51** extending therethrough. In the illustrated embodiment, upper shell **52** and lower shell **54** are substantially identical; however, it is contemplated that there could be differences between the upper and lower shells without deviating from the spirit and scope of the present invention. In the description that follows, the description of upper shell **12** also applies to lower shell **14**.

Referring further to FIGS. **8–9**, upper shell **52** includes ribs **58a, 58b, 58c, 58d, 58e, 58f**, collectively referred to as ribs **58**, and lower shell **54** includes ribs **59a, 59b, 59c, 59d, 59e, 59f**, collectively referred to as ribs **59**. While straight uninterrupted ribs **58, 59** are shown in the preferred embodiment, it is contemplated that other retention mechanisms such as barbs, interruptions, scales, etc., may be utilized to assist in retention and engagement of the upper and lower shells with the adjacent vertebral body. Upper shell **52** includes tapered leading surface **60** and tapered trailing surface **62**, and lower shell **54** includes tapered leading surface **61** and tapered trailing surface **63**. As explained further below, upper shell **52** and lower shell **54** each define a cavity or chamber to receive a portion of spacer **56**. In the preferred embodiment, the cavity in each shell is substantially rectangular when viewed in a top plan view.

Referring now to FIGS. **10–14**, upper shell **52** will be described in further detail, it being understood that lower shell **54** is similarly configured. The upper bone contacting surface of shell **52** is comprised of three separate regions. The first region is a partially cylindrical first lobe **80** having a first bone contacting surface **64** extending convexly along longitudinal axis **51** and interrupted by three ribs **58**. The second region is also a partially cylindrical second lobe **82** having a second bone contacting surface **68** that is substantially identical to bone contacting surface **64** extending substantially parallel with surface **64** and convexly along longitudinal axis **51**. Second surface **68** is interrupted by three additional ribs **58**. In the illustrated embodiment, three such ribs **58** are provided on each convex surface; however, a fewer number or greater number of retention ribs are also contemplated. The third region is an intermediate portion **84** interconnecting the partially cylindrical lobes of the first and second regions. Intermediate portion **84** includes a concave bone contacting surface **66** extending between first bone contacting surface **64** and second bone contacting surface **68**.

It will be understood that the combination of surfaces **64, 66, and 68** match a double-barrel insertion sleeve, including those insertion sleeves having a lumen that is figure eight or peanut shaped in cross-section. Implant **50** is placed through the insertion sleeve and into the disc space after reaming the adjacent vertebral end plates to form two substantially cylindrical holes spaced by a desired distance. The distance between the reamed holes in the end plate will determine the size of the intermediate portion **84** between first lobe **80** and second lobe **82**. Intermediate portion **84** will be reduced in size as the reamed holes in the disc space are positioned closer to provide the appropriate spacing between convex surfaces **64** and **68**. Conversely, as the distance between the reamed holes in the disc space increases, the intermediate portion **84** will be increased in size to provide the appropriate spacing between convex surfaces **64** and **68**.

As shown in FIGS. **12–13**, spacer retaining cavity **70** is formed by side walls **74** and **76**, flat internal load bearing surfaces **80** and **82**, a convex arcuate surface **78** extending between load bearing surface **80** and **82**, and end walls **72**

and **73**. In a preferred embodiment, width **W1** between side wall **74** and side wall **76** is greater than the width **W2** between leading end wall **72** and trailing end wall **73**. Cavity **70** has a maximum height **H4**. Spacer **56** has an upper surface configured for bearing contact with each of the surfaces **80, 82, and 78** in the upper shell **52** and a lower surface to match corresponding cavity bearing surfaces in lower shell **54**. As shown more clearly in FIGS. **8** and **9** and as described above with respect to implant **10**, greater than fifty percent of the overall height of spacer **56** is unconstrained by the upper and lower shells. Spacer **56** also has opposite sidewalls **69, 71** and opposite endwalls **65, 67** oriented vertically between upper shell **52** and lower shell **54** such that spacer **56** is confined entirely within upper shell **52** and lower shell **54** with no portion of spacer **56** extending outside the sidewalls and end walls of shells **52, 54**.

An alternate form of shell **52** is provided in FIG. **12a** and designated as **52'**. Shell **52'** is identical to shell **52**, except that cavity **70'** is defined by a relatively flat surface **80'** extending between leading end wall **72**, trailing end wall **73**, and sidewalls **74, 76**.

Referring now to FIGS. **15–17**, there is shown yet a further embodiment of an artificial disc implant according to the present invention. Implant **110** includes an upper shell **112**, a lower shell **114** separated by a spacer **116**. Upper shell **112** includes a number of ribs **118**, and lower shell **114** includes a number of ribs **119**. The outer configuration of the upper and lower shells **112** and **114** respectively, is substantially identical to the outer configuration of the upper and lower shells **52, 54** of implant **50**. Implant **110** differs from implant **50** with respect to the interior cavity adapted to engage spacer **116** and the configuration of spacer **116**.

Spacer **116** includes a first substantially cylindrical lobe **130**, a second substantially cylindrical lobe **132**, and an intermediate portion **134** joining lobes **130** and **132**. Preferably spacer **116** is formed as a homogenous unit, and the end view of spacer **116**, as shown in FIG. **16**, has a substantially figure-eight or peanut shaped configuration.

Referring now further to FIGS. **18–22**, there is shown upper shell **112**, it being understood that lower shell **114** is substantially identical to upper shell **112**, and lower shell **114** will not be further described. Upper shell **112** includes three separate regions. The first region is a first partially cylindrical lobe **123** having a first bone contacting surface **120** extending convexly along longitudinal axis **111** and interrupted by three ribs **118**. The second region is a second partially cylindrical lobe **125** having a second bone contacting surface **124** that is substantially identical to bone contacting surface **120**. Second bone contacting surface **124** extends substantially parallel with surface **120** and convexly along longitudinal axis **111**. Second surface **124** is interrupted by three additional ribs **118**. In the illustrated embodiment, three such ribs **118** are provided on each convex bone engaging surface; however, a fewer number or greater number of ribs are also contemplated. The third region is an intermediate portion **127** extending between and interconnecting the first and second cylindrical lobes. Intermediate portion **127** includes a concave bone contacting surface **122** extending between first surface **120** and second surface **124**.

Upper shell **112** includes an interior cavity **121** having a first lobe area **136** and a second lobe area **138**. Interior cavity **121** is defined by a first interior concave surface **126** extending along and substantially parallel to first bone contacting surface **120**, an interior convex surface **128** extending along and substantially parallel to exterior con-

cave surface **122**, and a second interior concave surface **129** extending along and substantially parallel to second bone contacting surface **124**. Cavity **121** is further bounded by a leading end wall **142** and an opposite trailing end wall **144**. Insert **116** is positionable in upper shell **112** and lower shell **114** with first lobe **130** in contact with first interior concave surface **126**, second lobe **132** in contact with second interior concave surface **129**, and intermediate portion **134** in contact with interior convex surface **128**. As previously disclosed with respect to embodiments **10** and **50**, the upper and lower shells do not constrain more than fifty percent of the height of spacer **116**.

Referring now to FIGS. **23–27**, there is shown a further embodiment of an artificial disc implant according to the present invention. Implant **150** includes an upper shell **152**, a lower shell **154**, and a spacer **156** therebetween. Similar to the spacer **116** of the previously described implant **110**, spacer **156** includes a first lobe **160** having a substantially cylindrical configuration, a second lobe **162** having a similar substantially cylindrical configuration, and an intermediate portion **164** joining each of the lobes. As described above with respect to implant **110**, the internal cavities of upper shell **152** and lower shell **154** are adapted to substantially match the configuration of spacer **156**. Similarly, shell **152** includes matching cylindrical lobes **180** and **182** interconnected by intermediate portion **181**, and lower shell **154** has cylindrical lobes **184** and **186** interconnected by intermediate portion **185**. It is further contemplated that implant **150** can have a configuration for spacer **156** and upper and lower shells **152**, **154** similar to that described above with respect to implant **50**.

As shown in FIGS. **25** and **27**, implant **150** may further include a flexible membrane **158** extending between and connected to the trailing end walls of upper shell **152** and lower shell **154**, and an opposite membrane **159** extending between and connected to the leading end walls of upper shell **152** and lower shell **154**. Membranes **158** and **159** may act to limit movement of spacer **156** between the upper and lower shells and expulsion of spacer **156** therefrom. Further, membranes **158** and **159** limit movement of the upper and lower shells with respect to one another. In a preferred embodiment, membranes **158** and **159** are composed of a braided material. It is contemplated that the braided membranes may be substantially flexible in tension, and outwardly flexible as spacer **156** is compressed. In a further embodiment, a flexible membrane is provided entirely about the spacer between the upper and lower shells.

In another aspect of this embodiment, an upper flange **165** is provided on the trailing end of upper shell **152** extending between lobes **180** and **182**. In a similar manner, a lower flange **167** is provided on a trailing end of lower shell **154** extending between lobes **184** and **186**. As shown more clearly in FIG. **27**, upper flange **165** includes an aperture **166** formed therethrough at an upwardly extending angle **A1** with respect to a longitudinal axis **151**. A screw **170** is insertable through aperture **166** at angle **A1** to threadingly engage the bony structure of the adjacent vertebral body to anchor upper shell **152** thereto. In a similar manner, lower flange **167** has a downwardly extending aperture **168** extending at an angle **A2** with respect to longitudinal axis **151**. A screw **172** is insertable through aperture **168** to engage the bony structure of the adjacent vertebral body to anchor lower shell **154** thereto.

Referring now to FIGS. **28–32**, there is shown an artificial disc implant according to another aspect of the present invention. Implant **210** includes an upper shell **212**, a lower shell **214**, and a spacer **216** therebetween. Similar to the

embodiment shown in FIG. **1**, the upper and lower shells are partially cylindrical and the entire implant **210** forms a substantially cylindrical structure. Upper shell **212** includes a thread pattern **218** defined on the outer surface that corresponds and aligns with a similar thread pattern **220** formed on lower shell **214**. Thus, implant **210** may be threaded into a disc space with the threads engaging the bony structure of the adjacent vertebrae. Spacer **216** has a cylindrical shape and is formed of an elastomeric compound, more preferably a hydrogel, and is retained within a cylindrical chamber formed by upper and lower shells **212**, **214**. Upper shell **212** defines a cavity extending between end walls **220** and **222**, and lower shell **214** has a cavity extending between end walls **224** and **226**. The end walls restrict movement of spacer **216** with respect to upper shell **212** and lower shell **214** and prevent expulsion of spacer **216** therefrom.

Referring now to FIG. **33**, there is shown another embodiment of an artificial disc implant according to the present invention. Implant **230** includes an upper shell **232**, a lower shell **234**, and a spacer **236** therebetween. Implant **230** is substantially cylindrical with the upper and lower shells each defining partially cylindrical portions. The exterior surfaces of upper and lower shells **232**, **234** are not uninterrupted with ribs but rather are roughened to create a bone engagement surface. In addition, it is contemplated that the surfaces could be formed such that there may be at least partial bone in-growth into the surface of the shells to assist in anchoring implant **230** in the disc space. The surfaces may further be coated with a BMP substance or other bone growth material to enhance bone growth.

Referring now to FIG. **34**, there is shown another embodiment of an artificial disc implant according to the present invention. Implant **240** includes an upper shell **242**, a lower shell **244**, and a spacer **246** therebetween. Upper shell **242** includes a single rib **248** extending longitudinally along implant **240**, and lower shell **244** includes a corresponding single rib **250** extending longitudinally along implant **240**. Ribs **248**, **250** engage the bony structure of the adjacent vertebral bodies.

Referring now to FIG. **35**, there is shown another embodiment of an artificial disc implant according to the present invention. Implant **260** includes an upper shell **262**, a lower shell **264**, and a spacer **266** therebetween. Upper shell **262** includes a lower edge **263** having a first extension **268** and a second extension **272** extending therefrom towards lower shell **264**. Lower shell **264** includes an upper edge **265** having a side wall recess **270** and an end wall recess **272** formed downwardly therein. Recess **270** corresponds to the location of extension **268**, and recess **274** corresponds to the location of extension **272**. Extensions and recesses may similarly be provided on the end and side of implant **260** not illustrated in FIG. **35**. When implant **240** is compressed, positioning of extension **268** in recess **270** will limit movement in the direction of arrows from **A** to **P** (anterior to posterior). In a similar fashion, positioning of extension of **272** in recess **274** will limit movement in the direction of arrows **L** to **R** (left and right). This limits displacement of the upper and lower shells relative to one another, and also limits shear stresses in spacer **266**. While both extensions are shown on upper shell **262**, it is contemplated that the combination of extensions and recesses may be alternatively formed in either the upper or lower shells without deviating from the teaching of the present invention. Furthermore, while arcuate recesses and extensions are shown, other configurations and shapes for the recesses and extensions may be utilized, including more closely engaged structures.

Referring now to FIGS. 36a, 36b, and 37, there is shown another embodiment of an implant of the present invention. FIG. 36a shows a cross-section of an artificial disc implant 300 having upper shell 302, lower shell 304, and an intervening spacer 306. As shown in FIG. 36b, spacer 306 includes an upper arcuate surface 316 and a lower arcuate surface 318. The upper and lower arcuate surfaces 316, 318 are adapted to engage the interior arcuate surfaces of upper shell 302 and lower shell 304, respectively. Insert 306 further includes truncated side walls 308 and 309 extending between upper arcuate surface 316 and lower arcuate surface 318. As shown in FIG. 36a, truncated side wall 308 is positioned adjacent the gap between lower edge 313 of upper shell 302 and upper edge 315 of lower shell 304, and truncated sidewall 309 is positioned adjacent the gap between lower edge 312 of upper shell 302 and upper edge 314 of lower shell 304. These gaps between upper shell 302 and lower shell 304 have a distance 310 when implant 300 is in a relaxed condition and little or no compressive force is applied between the upper and lower shells. As shown in FIG. 37, when significant compressive force F is applied to the upper and lower shells 302 and 304, the edges 313, 315 and the edges 312, 314 come closer together or even into contact, limiting the overall height displacement of implant 300. By providing spacer 306 with truncated side walls 308, 309 pinching of spacer 306 between edges 312, 314 and edges 313, 315 is substantially avoided. Pinching is further limited or prevented by extending the edges of the upper and lower shell laterally beyond the truncated portions of spacer 306.

Reference will now be made to the implants shown in FIGS. 38–41. FIG. 38 illustrates implant 350 having a substantially rectangular or square upper shell 352 and a substantially rectangular or square lower shell 354. A substantially rectangular or square spacer 356 is positioned between upper shell 352 and lower shell 354. In a similar manner, FIG. 39 shows an implant 360 having rectangular or square upper and lower shells 362, 364 and a substantially rectangular or square spacer 366 therebetween. Implant 360 further includes projections 368 extending from upper shell 361, and lower shell 364 includes recesses 370. The recesses 370 receive a corresponding one of the projections 368 as implant 360 is compressed, limiting displacement of the upper and lower shells and the shear forces in spacer 366 as previously described above with respect to implant 260 of FIG. 35.

FIG. 40 discloses a substantially circular implant 380 according to the present invention. Implant 380 includes circular upper shell 382 and circular lower shell 384, and intervening spacer 386 therebetween. In a similar manner, FIG. 41 shows a substantially circular implant 390 having circular upper shell 392 and circular lower shell 394 and a cylindrical spacer 396 therebetween. Implant 390 further includes projections 398 and recesses 399 configured to receive a corresponding one of the projections 398 as implant 390 is compressed. This limits the relative displacement of the upper and lower shells and the shear forces in spacer 396 as previously described above with respect to implant 260 of FIG. 35.

Referring now to FIGS. 42 and 43, there is shown a further embodiment of an artificial disc implant of the present invention. FIG. 42 illustrates implant 400 having a partially cylindrical upper shell 402, corresponding lower shell 404, and spacer 406 therebetween. Spacer 406 has a substantially cylindrical shape. Upper shell 402 includes a first lower edge 408 and opposite second lower edge 409. Lower shell 404 includes a first upper edge 410 and opposite

upper edge 411. With implant 400 in the relaxed condition shown in FIG. 42, the lower edges and upper edges are spaced by a distance 412. When a force is applied to implant 400 tending to compress it as shown in FIG. 43, the lower edges and upper edges become spaced by substantially smaller distance 414. A further feature of implant 400 is that the radius of curvature of spacer 406 is substantially less than a radius of curvature of both upper shell 402 and lower shell 404, and the elastic properties of spacer 406 are selected such that the overall compression of the spacer is limited under the maximum expected load such that distance 414 is the closest the edges of upper shell 402 and lower shell 404 will come toward each other. In this manner, pinching of spacer 406 is prevented.

Referring now to FIGS. 44–45, there is shown yet a further embodiment of an artificial disc implant. Implant 450 includes an upper shell 452, a lower shell 454 and a spacer 456 therebetween. Upper shell 452 includes a bottom surface formed by a series of ridges 458 extending toward lower shell 454. In a similar manner, lower shell 454 includes an upper surface formed by a series of ridges 460 extending toward upper shell 452. The upper and lower surfaces of spacer 456 are likewise ridged to mate with the ridges and valleys formed in the bottom surface of upper shell 452 and the upper surface of lower shell 454. With implant 450 in a relaxed condition shown in FIG. 44, the lower edge 462 of upper shell 452 is spaced from upper edge 464 of lower shell 454 by a distance 466. As the maximum expected compressive force is applied to implant 450, the upper edge 464 and lower edge 462 become spaced by a distance 468 that is substantially less than relaxed distance 466. The elastic properties of spacer 456 are selected such that the overall compression of the spacer is limited under the maximum expected load such that distance 466 is the closest the edges will come toward each other. In this manner, pinching of spacer 406 is prevented.

Utilization of implants according to the present invention will now be further described. It will be understood that access to the disc space, disc removal, and end plate preparation are known in the art and will only be briefly described herein. For example, procedures and instruments useable in a posterior approach to the disc space are disclosed in U.S. patent application Ser. No. 09/179,999, filed Oct. 27, 1998, assigned to the assignee of the present invention, and a publication by Sofamor Danek ©1996 entitled “Surgical Technique using Bone Dowel Instrumentation for Posterior Approach”, each of which is incorporated herein by reference in its entirety.

Referring now to FIGS. 46 and 47, there is shown looking posteriorly a disc space 500 positioned between an upper vertebral body V1 and a lower vertebral body V2. The anterior side of the vertebral bodies is indicated by the letter “A” and the posterior side is indicated by the letter “P”. As shown in FIG. 46, two separate implants 510 and 520 are inserted into the disc space, it being understood that implants 510 and 520 can be any of the implant embodiments described herein.

A first implant position may be prepared by removing disc material from disc space 500 and forming, by reaming, cutting, tapping or other technique, arcuate portion 516 in vertebral body V1. In procedures utilizing an insertion sleeve, such as sleeve 530, a laminectomy or facetectomy can also be performed through the sleeve. Similarly, a corresponding and aligned arcuate portion 518 is formed in vertebral body V2. Implant 510 may then be inserted with upper shell 512 contacting and/or engaged in arcuate recess 516, and lower shell 514 contacting and/or engaged in

arcuate recess **518**. The insertion sleeve **530** can maintain the implant in a reduced-size configuration during insertion through the sleeve by providing sleeve **530** with a channel **532** having a size that is less than the relaxed size of implant **510**. The intervening elastic spacer **519** is thereby held securely between the upper vertebral body **V1** and the lower vertebral body **V2**. A similar installation is performed with respect to implant **520** with upper shell **522** securely contacting and/or engaged in upper vertebral body **V1** and lower shell **524** contacting and/or engaged in lower vertebral body **V2**.

As shown in FIG. **47**, portions of bony material can remain anteriorly and posteriorly of implant **510** to countersink implant **510** in the disc space and further resist expulsion from the disc space. Such a placement of two separate implants in the disc space as illustrated is more typically performed during procedures that utilize a posterior approach to the disc space. Implants **510** and **520** can also be inserted into the disc space via a posterior approach through single barrel a tube or insertion sleeve **530** via pushing or threading the implants into position through sleeve **530**. By inserting two implants in the disc space, each implant will act independently to provide three degrees of motion, while the upper and lower shells protect the spacer from excessive wear or expulsion.

Referring now to FIG. **48**, there is shown a disc space **610** between vertebral bodies and an implant **612** configured for insertion through a double-barrel insertion sleeve **614**. Implant **612** can be any one of the implants **50**, **110** or **150** described above. Further, implant **612** can include any structure with a configuration that matches the configuration of interior channel **616** of sleeve **614**. The procedure shown in FIG. **48** is performed by an anterior-lateral approach to the disc space **610**, although anterior and lateral approaches are contemplated as well. Procedures and instruments useable in an anterior approach are disclosed in U.S. patent application Ser. No. 09/287,917, filed Apr. 7, 1999, assigned to the assignee of the present invention, and a publication by Sofamor Danek ©1996 entitled "Surgical Technique using Bone Dowel Instrumentation for Anterior Approach", each of which is incorporated herein by reference in its entirety.

Interior channel **616** of insertion sleeve **614** and implant **612** may be sized such that implant **612** is maintained in an at least partially compressed condition during insertion, allowing insertion of implant **612** into the disc space in a reduced height state. It will be understood that the end plates of the adjacent vertebral bodies to disc space **610** are prepared to receive implant **612** prior to implant insertion. Techniques for shaping the vertebral end plates to conform to the geometry of devices positioned in the disc space are well-known in the art and will not be further described herein. It is preferred that the locations for the cylindrical lobes of implant **612** are prepared by reaming the disc space, and further that the reamed implant location will allow the implant to be countersunk into the vertebral bodies to prevent expulsion of the implant from the disc space. Once implant **612** is inserted, the spacer will expand so that the upper and lower shells contact and/or engage the vertebral endplates to maintain implant **612** in disc space **610**.

Referring now to FIGS. **49a-51**, various implants are shown to accommodate various approaches for inserting the implants into the disc space. For the purposes of clarity the upper and lower shells of the implants are not illustrated in order to more clearly show the orientation and relative sizes of the implant spacers in the disc space. It should be understood that the illustrated spacers could be used with any of the implant embodiments described herein. It should

be further understood that the implant spacers may be provided as separate components as shown in FIGS. **49a-5b** or interconnected by an intervening spacer portion extending therebetween.

Referring more specifically to FIG. **49a**, there is shown an implant **700** inserted via an anterior approach to the disc space. More specifically, it is contemplated an implant inserted with this approach and having this configuration is inserted between the **L5** and **S1** vertebral bodies, although other vertebral levels are also contemplated. For such an approach, the spacers **702** in implant **700** may have a substantially tapered or truncated trapezoidal shape, as shown in FIG. **49b**, to establish and/or maintain the appropriate lordosis between the vertebral bodies with the posterior end of the spacer smaller than the anterior end of the spacer.

Referring now to FIG. **50a**, an anterior-lateral approach to the disc space is taken to insert implant **710** in the disc space. More specifically, it is contemplated an implant inserted with this approach and having this configuration can have particular application between the **L4** and **L5** vertebral bodies, although other vertebral levels are also contemplated. In this approach implant **710** has an anterior spacer **712** with a substantially tapered or trapezoidal shape, while the posterior spacer **714** has a substantially cylindrical shape, as shown in FIG. **50b**, to establish and/or maintain the appropriate lordosis between the vertebral bodies.

Referring now to FIG. **51a**, an implant **720** is positioned in the disc space by a substantially lateral approach. As shown in FIG. **51b**, implant **720** includes an anterior spacer **722** and a posterior spacer **724**. The difference in diameters between spacers **722** and **724** is provided to establish and/or maintain the appropriate lordosis between the vertebral bodies. This configuration would be particularly adapted to insertion of implant **720** between vertebral bodies **L1** and **L5**, although insertion at other vertebral levels is also contemplated.

Referring now to FIGS. **52** and **53**, there is shown a further embodiment of an artificial disc implant of the present invention. Implant **800** includes an upper shell **802** and a lower shell **804**. Upper shell **802** includes a first partially cylindrical lobe **810** interconnected with a smaller second partially cylindrical lobe **812** via intermediate portion **811**. Lower shell **804** similarly includes a first partially cylindrical lobe **814** interconnected with a smaller second partially cylindrical lobe **816** via intermediate portion **813**. Intermediate portions **811**, **813** can be provided with varying sizes as needed to achieve the desired spacing between the first and second lobes of shells **802**, **804**, respectively. A number of ribs **818** extend from first lobes **810**, **814** and a number of ribs **819** extend from second lobes **812**, **816**. A first spacer **806** is positioned between first lobe **810** of upper shell **802** and first lobe **814** of lower shell **804**. A second spacer **808** is positioned between second lobe **812** of upper shell **802** and second lobe **816** of lower shell **804**.

First spacer **806** has a height **H4** that is greater than a height **H5** of second spacer **808**. First spacer **806** further has a length **L4** that is greater than length **L5** of second spacer **808**. First lobes **810** and **814** are configured to accommodate first spacer **806**, and first lobes **810**, **814** can be provided with endwalls to prevent spacer **806** from protruding or expelling therefrom. Second lobes **812** and **816** are configured to accommodate second spacer **808**, and second lobes **812**, **816** can be provided with endwalls to prevent spacer **808** from protruding or expelling therefrom. Implant **800** would be particularly suited in a lateral approach to the disc

space as discussed above, with first spacer **806** positioned toward the anterior side of the disc space and second spacer **808** positioned towards the posterior side of the disc space. In another embodiment, it is contemplated that an intervening portion may be provided between first spacer **806** and second spacer **808** to connect the first and second spacers forming a single spacer body.

Referring now to FIGS. **54a–54d**, a method for inserting an implant through a double barrel sleeve via a lateral approach to the disc space will now be described. It is contemplated that the method uses double barrel sleeve **612**, such as that shown in FIG. **48**, to provide an implant insertion path to the disc space. In one specific embodiment, sleeve **612** includes overlapping working channel portions, such as the double barrel sleeve described in pending U.S. patent application Ser. No. 09/498,426, filed Feb. 4, 2000, which is incorporated herein by reference in its entirety. It is further contemplated that the implant inserted according to this technique can be any of the above-described implants, although preferably the implant is one of the embodiments having a pair of interconnected cylindrical lobes. It is further contemplated that aspects of the described techniques also have application with anterior and anterior-lateral approaches.

In FIG. **54a**, a starting point **902** is established with respect to the disc lateral annulus posterior to the midline of the disc. The position of the starting point can be confirmed with a target template fluoroscopically or radiographically. A trephine is inserted to the starting point to incise the disc annulus at the starting point. In FIG. **54b**, an anterior annulus incision **904** is made vertically in the annulus, and a distraction plug **906** inserted through the starting point incision to distract the disc space to the desired height. In an alternate form, a second distraction plug is inserted anteriorly with respect to distraction plug **906**.

In FIG. **54c**, double barrel sleeve **614** is inserted over a stem (not shown) extending from distraction plug **906**. Preferably, sleeve **614** has tangs **618** and **620** (FIG. **48**) that are inserted into the disc space. Preferably, shorter tang **618** is positioned posteriorly and longer tang **620** is positioned anteriorly. It is further contemplated that anterior tang **620** can have a height larger than posterior tang **618** to assist in establishing lordosis. It is further contemplated that the distal end of sleeve **614** can include inferior and superior spikes **622** that can be embedded in inferior vertebra **V2** and superior vertebra **V1**, respectively, to hold the vertebrae at the desired spacing during the procedure.

Distraction plug **906** is removed from sleeve **614** and the disc space reamed via a reamer inserted through the respective working channel portions of sleeve **614** to formed posterior reamed location **908** and anterior reamed location **910**. If an implant similar to implant **800** is provided, or if separate implants of differing lengths are provided, the disc space is reamed to a greater depth through the anterior working channel portion to accommodate the longer implant portion. When reaming is complete, the reamer is removed, as shown in FIG. **54d**, and the implant positioned in the working channel of sleeve **614**. If necessary, the implant can be compressed from its relaxed state for insertion into working channel **616**.

As shown in FIG. **54e**, implant **912** is pushed through working channel **616** via an impactor and into the disc space. Positioning of the implant in the disc space can be confirmed via fluoroscopic or radiographic instrumentation. When the implant is in the desired position, a braided fabric material **914** can be secured to vertebral bodies **V1** and **V2** across the

entry into the disc space to further resist implant expulsion from the disc space.

The present invention contemplates providing a variety of sizes and shapes of spacers for utilization with upper and lower shells to achieve the necessary angulation between vertebral bodies and to take into account the surgeon's access to the disc space. Further, while the above described combinations have been disclosed herein as being applicable to particular disc space, this is not a limitation on the use of such devices and uses in other manners or other disc space is contemplated as being within the spirit of the present invention.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character; it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. An artificial disc implant, comprising:

an upper shell having a first portion with a first convex bone contacting surface, a second portion with a second convex bone contacting surface, and a middle portion having a concave bone contacting surface extending between said first portion and said second portion, said upper shell having a cavity formed therein;

a lower shell having a first portion with a first convex bone contacting surface, a second portion with a second convex bone contacting surface, and a middle portion having a concave bone contacting surface extending between said first portion and said second portion, said lower shell having a cavity formed therein; and

a compressible spacer supporting said upper shell and said lower shell positioned in said cavities of said upper shell and said lower shell.

2. The artificial disc implant of claim 1, wherein:

said upper shell includes at least one rib extending along said first portion and at least one rib extending along said second portion; and

said lower shell includes at least one rib extending along said first portion and at least one rib extending along said second portion.

3. The artificial disc implant of claim 2, wherein each of said ribs includes a tapered leading end and a tapered trailing end.

4. The artificial disc implant of claim 2, wherein said ribs are continuous.

5. The artificial disc implant of claim 1, wherein said spacer is elastic.

6. The artificial disc implant of claim 5, wherein said spacer is made from an elastomeric compound.

7. The artificial disc implant of claim 5, wherein said spacer has a hydrogel core.

8. The artificial disc implant of claim 7, wherein said hydrogel core is dehydratable to reduce the implant height.

9. The artificial disc implant of claim 1, wherein said upper shell and said lower shell are each made from a biocompatible material selected from the group consisting of: stainless steel, titanium, shape memory alloys, polymers, carbon fiber, and porous material.

10. The artificial disc implant of claim 1, wherein:

said upper shell includes a leading end wall and an opposite trailing end wall, each of said upper shell end walls extending along said first portion, said second portion, and said middle portion of said upper shell and further extending towards said lower shell; and

17

said lower shell includes a leading end wall and an opposite trailing end wall, each of said lower shell end walls extending along said first portion, said second portion, and said middle portion of said lower shell and further extending towards said upper shell, whereby said end walls of said lower shell and said end walls of said upper shell resist expulsion of said spacer from said cavities of said upper shell and said lower shell.

11. The artificial disc implant of claim **10**, wherein:

said leading end and said trailing end of said upper shell are tapered; and

said leading end and said trailing end of said lower shell are tapered.

12. The artificial disc implant of claim **1**, wherein:

said cavity of said upper shell is defined by an arcuate surface that substantially parallels said first convex bone contacting surface, said second convex bone contacting surface, and said concave bone contacting surface; and

said cavity of said lower shell is defined by an arcuate surface that substantially parallels said first convex bone contacting surface, said second convex bone contacting surface, and said concave bone contacting surface.

13. The artificial disc implant of claim **1**, wherein:

said upper shell includes a leading end wall and an opposite trailing end wall, said upper shell further including an upper flange at said trailing end wall extending upwardly from said concave surface of said middle portion, said upper flange having an aperture therethrough to receive a bone screw to engage said upper shell to an upper vertebral body; and

said lower shell includes a leading end wall and an opposite trailing end wall, said lower shell further including a lower flange at said trailing end wall extending downwardly from said concave surface of said middle portion, said lower flange having an aperture therethrough to receive a bone screw to engage said lower shell to a lower vertebral body.

14. The artificial disc implant of claim **13**, wherein said upper flange aperture has a central axis that extends upwardly and towards said leading end at an angle **A1** from a longitudinal axis of the implant, and said lower flange aperture has a central axis that extends downwardly and towards said leading end at an angle **A2** from the longitudinal axis of the implant.

15. An artificial disc implant, comprising:

an upper shell having a leading end, a trailing end, a longitudinal axis extending therebetween, and an arcuate upper bone contacting surface extending between said leading end and said trailing end about said longitudinal axis, said upper shell having a cavity formed therein opposite said upper surface, said upper shell further including at least one rib extending upwardly from said upper surface and generally in the direction of the longitudinal axis engageable in bone of an upper vertebral endplate when positioned in the disc space;

a lower shell having a leading end, a trailing end, a longitudinal axis extending therebetween, and an arcuate lower bone contacting surface extending between said leading end and said trailing end about said longitudinal axis, said lower shell having a cavity formed therein opposite said lower surface, said lower shell further including at least one rib extending downwardly from said lower surface and generally in the

18

direction of the longitudinal axis engageable in bone of a lower vertebral endplate when positioned in the disc space; and

a compressible spacer positioned in said cavities of said upper shell and said lower shell.

16. The artificial disc implant of claim **15**, wherein said upper shell includes three ribs and said lower shell includes three ribs.

17. The artificial disc implant of claim **15**, wherein:

said leading end and said trailing end of said upper shell are tapered; and

said leading end and said trailing end of said lower shell are tapered.

18. The artificial disc implant of claim **17**, wherein:

said leading end and said trailing end of said at least one rib of said upper shell are tapered; and

said leading end and said trailing end of said at least one rib of said lower shell are tapered.

19. The artificial disc implant of claim **15**, wherein:

said upper shell has a first height between said upper surface and a lower edge of said upper shell;

said lower shell has a second height between said lower surface and an upper edge of said lower shell; and

said spacer being constrained in said cavities of said upper shell and said lower shell, said spacer further having an unconstrained height between said lower edge of said upper shell and said upper edge of said lower shell.

20. The artificial disc implant of claim **19**, wherein said unconstrained height of said spacer is greater than the combination of said first height and said second height.

21. The artificial disc implant of claim **19**, wherein said spacer includes opposite concave sidewalls extending between said lower edge of said upper shell and said upper edge of said lower shell.

22. An artificial disc implant, comprising:

an upper shell having a cavity defined by a first partially cylindrical lobe, a second partially cylindrical lobe, and a middle portion extending therebetween;

a lower shell having a cavity defined by a first partially cylindrical lobe, a second partially cylindrical lobe, and a middle portion extending therebetween; and

a compressible spacer supporting said upper shell and said lower shell positioned in said cavities of said upper shell and said lower shell.

23. The artificial disc implant of claim **22**, wherein:

said upper shell includes a leading end wall and an opposite trailing end wall, each of said end walls extending between said first and second cylindrical lobes; and

said lower shell includes a leading end wall and an opposite trailing end wall, each of said end walls extending between said first and second cylindrical lobes.

24. The artificial disc implant of claim **22**, wherein said spacer includes a first spacer and a second spacer, wherein said first spacer is longer than said second spacer.

25. The artificial disc implant of claim **24**, wherein said first spacer and said second spacer are interconnected by an intervening portion extending therebetween.

26. The artificial disc implant of claim **22**, wherein said spacer includes a first spacer and a second spacer, wherein said first spacer of has a height greater than a height of said second spacer.

27. The artificial disc implant of claim **26**, wherein said first spacer and said second spacer are interconnected by an intervening portion extending therebetween.

19

28. The artificial disc implant of claim 22, wherein said spacer includes a first spacer and a second spacer each having a tapered height for insertion anteriorly into a disc space to establish lordosis.

29. The artificial disc implant of claim 22, wherein:
 said upper shell has a first height between an upper surface and a lower edge of said upper shell;
 said lower shell has a second height between a lower surface and an upper edge of said lower shell; and
 said spacer being partially constrained in said cavities of said upper shell and said lower shell along said shell height, said spacer further having an unconstrained height between said lower edge of said upper shell and said upper edge of said lower shell.

30. The artificial disc implant of claim 29, wherein said unconstrained height of said spacer is greater than the combination of said first height and said second height.

31. The artificial disc implant of claim 22, wherein:
 each of said lobes of said upper shell includes at least one rib extending upwardly therefrom; and
 each of said lobes of said lower shell includes at least one rib extending downwardly therefrom.

32. The artificial disc implant of claim 31, wherein each of said ribs is continuous along the length of said lobe.

33. An artificial disc implant, comprising:
 an upper shell having a leading end, a trailing end, and an arcuate upper bone contacting surface extending therebetween, said upper shell having a cavity formed therein opposite said upper surface, said upper shell further including three ribs extending upwardly from said upper surface and between said leading end and said trailing end;

a lower shell having a leading end, a trailing end, and an arcuate lower bone contacting surface extending therebetween, said lower shell having a cavity formed therein opposite said lower surface, said lower shell further including three ribs extending downwardly from said lower surface and between said leading end and said trailing end; and

a compressible spacer positioned in said cavities of said upper shell and said lower shell.

34. The artificial disc implant of claim 33, wherein:
 said leading end and said trailing end of said upper shell are tapered; and
 said leading end and said trailing end of said lower shell are tapered.

35. The artificial disc implant of claim 34, wherein:
 said leading end and said trailing end of each of said three ribs of said upper shell are tapered; and
 said leading end and said trailing end of each of said three ribs of said lower shell are tapered.

36. The artificial disc implant of claim 33, wherein:
 said upper shell has a first height between said upper surface and a lower edge of said upper shell;

20

said lower shell has a second height between said lower surface and an upper edge of said lower shell; and
 said spacer being constrained in said cavities of said upper shell and said lower shell, said spacer further having an unconstrained height between said lower edge of said upper shell and said upper edge of said lower shell.

37. The artificial disc implant of claim 36, wherein said unconstrained height of said spacer is greater than the combination of said first height and said second height.

38. The artificial disc implant of claim 36, wherein said spacer includes opposite concave sidewalls extending between said lower edge of said upper shell and said upper edge of said lower shell.

39. An artificial disc implant, comprising:
 an upper shell having a tapered leading end, a tapered trailing end, and an arcuate upper bone contacting surface extending therebetween, said upper shell having a cavity formed therein opposite said upper surface, said upper shell further including at least one rib extending upwardly from said upper surface and between said leading end and said trailing end;
 a lower shell having a tapered leading end, a tapered trailing end, and an arcuate lower bone contacting surface extending therebetween, said lower shell having a cavity formed therein opposite said lower surface, said lower shell further including at least one rib extending downwardly from said lower surface and between said leading end and said trailing end; and
 a compressible spacer positioned in said cavities of said upper shell and said lower shell.

40. The artificial disc implant of claim 39, wherein said upper shell includes three ribs and said lower shell includes three ribs.

41. The artificial disc implant of claim 39, wherein:
 said leading end and said trailing end of said at least one rib of said upper shell are tapered; and
 said leading end and said trailing end of said at least one rib of said lower shell are tapered.

42. The artificial disc implant of claim 39, wherein:
 said upper shell has a first height between said upper surface and a lower edge of said upper shell;
 said lower shell has a second height between said lower surface and an upper edge of said lower shell; and
 said spacer being constrained in said cavities of said upper shell and said lower shell, said spacer further having an unconstrained height between said lower edge of said upper shell and said upper edge of said lower shell.

43. The artificial disc implant of claim 42, wherein said unconstrained height of said spacer is greater than the combination of said first height and said second height.

44. The artificial disc implant of claim 42, wherein said spacer includes opposite concave sidewalls extending between said lower edge of said upper shell and said upper edge of said lower shell.

* * * * *